United States General Accounting Office

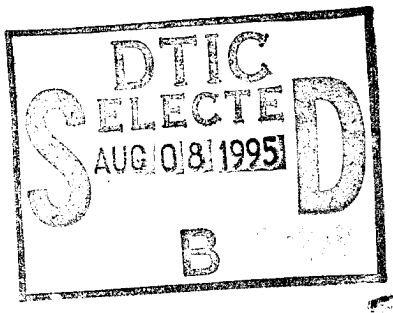
GAO

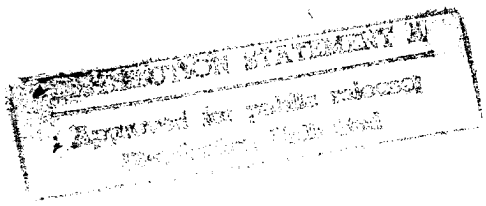
Report to the Chairman, Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

June 1992

# FOOD SAFETY AND QUALITY

# Uniform, Risk-based Inspection System Needed to Ensure Safe Food Supply



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**United States**
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**Washington, D.C. 20548**

**Resources, Community, and**
**Economic Development Division**

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June 26, 1992

The Honorable John D. Dingell
Chairman, Subcommittee on Oversight
and Investigations
Committee on Energy and Commerce
House of Representatives

Dear Mr. Chairman:

This report responds to your request that we examine the consistency, efficiency, and effectiveness of the federal food safety inspection system. Currently, as many as 35 different laws and 12 agencies shape the federal regulatory process for protecting the public health from unsafe food. We found that federal agencies (1) inspect foods posing similar risks at inconsistent frequencies and under different enforcement authorities, (2) use their inspection resources inefficiently, and (3) do not effectively coordinate their inspection efforts.

The report makes recommendations for eliminating the inconsistencies in food safety inspections and agencies' authorities, and improving the efficiency and effectiveness of agency inspections. It also recommends that the Congress hold oversight hearings to evaluate options for revamping the federal food safety system, such as creating a single food safety agency to administer a uniform set of food safety laws.

As arranged with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from the date of this letter. At that time, we will provide copies to the appropriate departmental secretaries, agency heads, and interested congressional committees. We will also make copies available to others upon request.

This work was performed under the direction of John W. Harman, Director of Food and Agriculture Issues, who may be reached at (202) 275-5138 if you or your staff have any questions. Other major contributors to this report are listed in appendix III.

Sincerely yours,

J. Dexter Peach
Assistant Comptroller General

# Executive Summary

## Purpose

The federal government spends about $1 billion a year to ensure the safety and quality of an estimated 275 billion meals that the nation consumes each year. This effort is achieved through a fragmentary, complex regulatory system consisting of as many as 35 different laws and involving 12 agencies. Concerned about the effectiveness of the federal food safety inspection system, the Chairman, Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, asked GAO to determine if (1) food inspection systems are logical and consistent, (2) agencies are efficiently using federal resources for inspection, and (3) agencies are effectively coordinating their food safety and quality inspection efforts.

## Background

Of the 12 federal agencies, 5 have primary responsibility for food safety and quality inspections; the specific food commodity determines which agency has oversight. The Food and Drug Administration (FDA) is responsible for the safety of most foods. Within the U.S. Department of Agriculture (USDA), the Food Safety and Inspection Service (FSIS) is responsible for ensuring the safety of meat and poultry products; the Agricultural Marketing Service (AMS) for ensuring the safety of eggs and egg products and for grading products such as fruits, nuts, and vegetables; and the Federal Grain Inspection Service (FGIS) for ensuring the safety of exported grain products and for grading domestic and imported grains and related commodities. The Department of Commerce's National Marine Fisheries Service (NMFS) is responsible for grading seafood products.

In general, food products under FDA's jurisdiction may be marketed without the agency's prior approval. Food products under USDA's regulatory jurisdiction, however, must generally be inspected and approved as meeting federal standards before being marketed.

## Results in Brief

Inconsistencies and illogical differences between the agencies' approaches and enforcement authorities undercut the system's effectiveness. How frequently a food processing plant is inspected and what actions are taken to enforce food safety standards are determined not by a unified, comprehensive assessment of the risk that specific food products pose to public health but by the legislation that governs the responsible agency. For example, firms that process meat and poultry (under FSIS' regulations) are inspected daily, while firms that process seafood, which may be of similar risk, are inspected about once every 3 to 5 years (under FDA's rules). In situations not specifically addressed by law, agencies often

determine who has jurisdiction to inspect food by administrative distinctions. For example, agencies have determined who has jurisdiction over inspecting a meat sandwich made with one slice of bread as opposed to a meat sandwich made with two slices of bread. FDA also lacks certain enforcement authorities granted to FSIS—for instance, the right to detain adulterated domestic products without a court order. Thus, FDA is hindered in its efforts to prevent unsafe foods from entering the nation's food supply.

Federal agencies responsible for food safety and quality inspections could use their resources more efficiently by basing inspection frequencies on risk—the potential hazards associated with the product, process, and processors' compliance with federal regulations—and by eliminating duplicative inspections. FSIS continues to inspect all meat and poultry processing plants daily, although it has been given legal authority, which expires in November 1992, to test the feasibility of reducing the frequency of inspections at plants where safety risks are lower. Furthermore, federal agencies' inspections of food plants may overlap: GAO found that FDA's inspections of plants that also process products under the jurisdiction of other agencies or that participate in other agencies' voluntary inspection and grading programs are often duplicative.

Coordination agreements—under which agencies are required to notify other responsible agencies of problems they encounter during inspections—do not ensure that food safety problems are corrected. Unsanitary and other unsafe conditions persist in food processing plants because such notifications do not always take place or the problems referred to the responsible agency are not always promptly investigated. Effective use of the agreements has been hindered by a lack of agency resources to complete follow-up investigations once a referral has been made and an absence of adequate internal systems for assigning and tracking reported problems.

Past efforts to correct deficiencies in the federal food safety inspection system have fallen short, in part, because the responsible agencies have continued to operate under different regulatory approaches. Agencies have also acted to protect their own jurisdictions, thus reducing their flexibility to respond to changing consumption patterns and emerging food safety issues, such as the control of food poisoning outbreaks associated with salmonella. A new structure for food safety inspection and enforcement, based on uniform enforcement authorities and an assessment of the risk that food products pose to public health, could help

the Congress oversee, fund, and enact legislation on the federal food safety inspection system.

# Principal Findings

## Diverse Regulatory Approaches Result in Inconsistent Oversight

Food products that pose virtually the same health risk to the public are inspected at widely different frequencies, depending on which agency—and thus which regulatory approach—governs them. Although FSIS and FDA acknowledge that there is virtually no difference in the potential health risk, meat and poultry plants regulated by FSIS are inspected daily or continuously, depending on the plants' operations, while processors of rabbit, venison, and quail, for example, which are under FDA's jurisdiction, are inspected about once every 3 to 5 years. Also, decisions on which agency has jurisdiction may be based on the amount of a particular food a product contains, so that soups containing 2 percent or more of cooked meat are inspected by FSIS, while soups containing less than 2 percent are inspected by FDA. Resource constraints, rather than an agreed assessment of risk, can also influence decisions on which agency will assume jurisdiction, precluding assignments of similar food products to one agency. For example, the decision for FSIS to have jurisdiction over meat and poultry sandwiches made with one slice of bread, while FDA has jurisdiction over traditional meat and poultry sandwiches—those with two slices of bread—was partly due to the resources that would be required for daily inspection of all plants producing traditional meat and poultry sandwiches.

Enforcement authorities granted to the agencies also differ. USDA agencies have the authority to (1) require food processors to register so that they can be inspected, (2) presume that food firms are involved in interstate commerce and are thus subject to regulation, (3) prohibit the use of processing equipment that may potentially contaminate food products, and (4) temporarily detain any suspect foods. Conversely, FDA, without such authority, is often hindered in its ability to oversee food processors. In fact, because firms under its jurisdiction are generally not required to register, FDA is not aware of and does not oversee or inspect some domestic food processors. FDA believes it needs additional authorities to ensure food safety, but the Department of Health and Human Services and the Office of Management and Budget have not forwarded FDA's legislative proposals to the Congress for consideration.

## Inspection Resources Are Not Efficiently Used

Federal agencies are not using their inspection resources efficiently. Because the frequency of inspection is based on the agencies' regulatory approach, some foods may be receiving too much attention, while other foods may not be receiving enough. Risk-based inspections could lead to safer products and reduce costs because scarce federal inspection resources could be redirected from low-risk operations to areas that may need greater coverage because they present a higher risk.

To redirect FSIS inspections toward the most risky firms and food processes, the Congress passed a 1986 law giving FSIS 6 years to test the concept of discretionary inspections—that is, inspections based on the agency's judgment of the health risk involved. However, FSIS has not implemented such inspections because its proposed regulations were initially opposed by industry, consumers, and others. FSIS estimated in its fiscal year 1990 budget justification that 148 staff years, costing an estimated $4.6 million annually, could be saved or directed to higher-risk areas by eliminating unnecessary inspections of some low-risk meat and poultry operations that are currently inspected daily.

Additional inefficiencies result from duplicative inspections. Food establishments may be inspected by more than one federal agency because they process foods that are regulated under different federal laws, or because they participate in voluntary inspection or grading service programs. GAO found that 514 of the 8,653 FDA inspections conducted in six states during the period October 1, 1987, through March 31, 1991, duplicated those of other federal agencies. For example, FSIS had five inspectors assigned full-time to a plant that processed soups containing meat or poultry, yet FDA inspected the same plant because it also processed soups that did not contain meat or poultry.

## Food Safety Agencies Do Not Effectively Coordinate Efforts

Because different agencies have regulatory responsibilities for specific foods and different agencies may inspect the same food plant, the agencies have entered into more than 25 agreements to coordinate their efforts. Although these agreements generally require that the responsible regulatory agency be promptly notified of any food safety problems, the agencies frequently do not make the required referrals. For example, NMFS did not notify FDA—the agency responsible for taking regulatory action—of 131 seafood plants that failed NMFS' inspections and thus were denied grading services. Agencies say they do not notify other agencies of problems because, among other things, the agreements lack specific instructions about whom to notify or are outdated.

Even when notifications take place, they may not always lead to timely investigations. For example, FDA did not investigate about 80 percent of 12,800 referrals made by one agency in 1989 and 1990. Although FDA policy calls for follow-up investigations of all referrals, the agency does not have a system for assigning and tracking the referrals, and believes it lacks the resources needed for prompt follow-up action.

## Revamping the Federal Food Safety Inspection System

The inconsistent, duplicative nature of the federal food safety inspection system has been recognized by GAO and other organizations over the past two decades. But the responsible agencies continue to operate under different food safety statutes. As a result, foods that pose similar health risks to the public are subject to significantly different inspection approaches, and resources cannot be reallocated among agencies to improve the consistency of inspections of food products or processes. Furthermore, the agencies' actions to protect their own interests prevent the coordination needed to address public health concerns associated with emerging food safety issues and the public's changing consumption patterns.

Because the federal regulatory system for food has evolved over the past century and will continue to evolve as food safety concerns emerge, it may now be time to review the structure of this system in terms of the number of laws and agencies involved and the priorities that have governed their regulatory approaches. Possible alternatives include (1) creating a single food safety agency to administer a uniform set of food safety laws, (2) creating a uniform set of food safety laws to be administered by current federal agencies, or (3) having a panel of experts develop a model for an inspection system based on public health risks and adequate enforcement powers as a way to facilitate broad-based agreement on preferred legislative and organizational changes needed to achieve a more rational and effective food safety system.

GAO's analysis of the advantages and disadvantages of the above alternatives indicates that the greatest benefits—in terms of improved effectiveness, efficiency, and uniformity—could be realized by creating a single food safety agency. GAO recognizes, however, that reaching agreement on such a major structural change would be difficult, at best, because the current system has been in place since the early 1900s and agencies, congressional committees, and regulated industries have a strong allegiance to the present system. Thus, a more realistic approach may be the creation of a blue-ribbon panel to develop a model that could

provide decisionmakers with a stronger position to argue for and implement structural and legislative changes.

## Recommendations

GAO is making a number of recommendations to departmental secretaries and agency heads to, among other things, eliminate inconsistencies in agencies' inspection schedules and enforcement authorities, increase the efficient use of resources by eliminating unnecessary and duplicate inspections, and improve interagency coordination. These recommendations are detailed in chapters 3 and 4.

## Recommendation to the Congress

Without basic changes to the federal regulatory structure and food safety laws, the problems identified above are likely to continue. Therefore, GAO recommends that the Congress hold oversight hearings to evaluate options for revamping the food safety and quality system, including the three options discussed above. Matters for congressional consideration are contained in chapters 2 and 3.

## Agencies' Comments

GAO discussed the information in this report with responsible officials of the five major food safety and quality agencies, who generally agreed with the facts as presented. Where appropriate, changes were made on the basis of these discussions to update and clarify some of the information. However, as requested, GAO did not obtain written agency comments on a draft of this report.

# Contents

**Abbreviations**

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| AMS | Agricultural Marketing Service |
| FDA | Food and Drug Administration |
| FFDCA | Federal Food, Drug, and Cosmetic Act |
| FGIS | Federal Grain Inspection Service |
| FSIS | Food Safety and Inspection Service |
| GAO | General Accounting Office |
| HHS | Department of Health and Human Services |
| NMFS | National Marine Fisheries Service |
| OMB | Office of Management and Budget |
| USDA | U.S. Department of Agriculture |

# Introduction

Ensuring the safety and quality of an estimated 275 billion meals that the nation consumes each year and overseeing the industries that produce and process our foods have been important, growing federal responsibilities for nearly a century. Over the years, the federal role in regulating food safety has been shaped by reliance on traditional jurisdictional divisions, ad hoc reactions to emerging health concerns, and responses to technological developments into a dispersed, highly complex system governed by as many as 35 laws and administered by 12 federal agencies. The federal system is supplemented by the states, which have their own statutes, regulations, and agencies to regulate and inspect the safety and quality of food products.

Despite this extensive governmental effort and the belief that generally the United States has the safest food supply in the world, food safety remains a concern. Not only do questions persist about the long-range effects of pesticide residues, food additives, and natural toxins in food, but outbreaks of food-borne illness highlight the immediate dangers of microbiological contamination of food. The federal Centers for Disease Control estimates that more than 9,000 people a year die from food-borne illness, and the Centers and others estimate that between 6 million and 33 million Americans suffer from food-related illnesses each year. For example, in 1985, 47 people died and another 140 became ill from consuming cheese contaminated with listeria—a pathogenic bacteria. Also in 1985, as many as 12 deaths and an estimated 180,000 illnesses were caused by the consumption of milk contaminated with salmonella. More recently, in 1989, more than 100 people suffered illnesses—16 requiring hospitalization—from consuming imported canned mushrooms containing the staphylococcus bacteria, and in 1991 over 400 people in the United States and Canada became ill from eating cantaloupes contaminated with salmonella. In addition, consumers have also been alarmed by media reports of eggs and poultry contaminated with salmonella. Suggested approaches for improving food safety have ranged from developing better testing methods to educating consumers on the proper handling of food in the home.

## Federal Food Safety Laws, Agencies, and Responsibilities

The federal regulatory role for food safety has increased substantially over the past century as food processing and preparation moved out of the home and into the factory. In the early 1900s, food processing—such as smoking meat or canning produce—was still done at home. As more food-processing operations moved to the factory and food was shipped to market for longer distances, consumers bought factory-processed foods

rather than locally grown staples. This trend toward the consumption of factory-processed foods continues today, with "ready-to-eat" foods making up the fastest growing segment of retail food sales.

This increasing reliance on processed foods has had important consequences for food safety. First, the responsibility for ensuring food safety has shifted away from consumers to processors, retailers, and regulators. Second, if something goes wrong in the manufacturing process or food service establishment, yielding an unsafe food product, many more people could potentially be harmed than through the mishandling of food by an individual cooking at home.

Along with the changes in responsibility for food safety have come changes in the approach of federal food safety regulation. Traditionally, the law allowed food firms to produce, process, and market their products without the prior approval of the federal government. Usually only when products were later found to be contaminated or otherwise unfit for human consumption did the federal government step in to stop distribution or remove the product from interstate commerce. Gradually, however, in response to various food safety crises and problems, the federal government began to require that before certain products could be marketed they had to be "approved," that is, inspected for compliance with federal standards. This significant change in regulatory approach essentially created two separate regulatory processes (one in which products had to be approved before marketing and one in which the government reacted principally when unsafe foods were found) that are administered by different agencies, with different responsibilities, authorities, and enforcement powers.

Laws governing the U.S. Department of Agriculture (USDA), which were usually enacted in response to a crisis in food safety, require the food industry to demonstrate to government inspectors that their food products are safe and wholesome. Laws enacted that require preapproval include (1) the Federal Meat Inspection Act of 1907 (the meat act), enacted in the wake of public outcry over unsanitary meat packing conditions described in Upton Sinclair's 1906 novel The Jungle; (2) the Poultry Products Inspection Act of 1957 (the poultry act), created to deal with greater food safety risks associated with increased poultry consumption and the introduction of large-scale poultry production methods; and (3) the Egg Products Inspection Act of 1970 (the egg act), passed in response to the outbreak of illnesses attributed to salmonella-contaminated eggs and egg products in the late 1960s.

By contrast, the laws that govern the Food and Drug Administration (FDA), which derive from the first comprehensive food safety law enacted in 1906, require FDA to prove that a food is contaminated, held under unsanitary conditions that could lead to contamination, or otherwise shown to be unfit for human consumption. Regulatory changes made in the past two decades have also increased oversight of some products regulated by FDA. In the early 1970s, after several life-threatening outbreaks of botulism caused by the improper processing of low-acid and acidified canned foods, FDA established new regulations for these products. Processors of low-acid and acidified canned foods sold in the United States are now required to register with FDA and to file a description of the processes they intend to use in making these foods. Similarly, in 1980, after numerous illnesses caused by infant formulas deficient in chloride, the Congress passed the Infant Formula Act of 1980. This act requires any processor to register with FDA before producing infant formula and/or revising its formulation.

The trend toward increased oversight appears to be continuing. According to a December 1990 Congressional Research Service report, recently proposed seafood inspection programs, among other things, contain provisions for product sampling and testing and require all processing establishments to be certified by the government and to meet minimum sanitation and quality control, labeling, and record-keeping rules.[1] Although five congressional committees approved separate seafood inspection bills and the House of Representatives and the Senate passed seafood inspection bills in 1990, a conference committee was not convened to produce a compromise bill.

As a result of the evolution of federal food safety legislation and regulatory approach, 12 federal agencies each have some responsibility for food safety or quality, and each operates under different legislative mandates and regulatory guidance. Although specific data on the amount the federal government spends on food safety and quality inspection activities are not readily available, we estimate that these agencies spend about two-thirds of their $1 billion food safety and quality budgets to inspect and test our food supply. Five of the agencies perform most of the federal food safety and quality activities—FDA, which is part of the Department of Health and Human Services (HHS); USDA's Food Safety and Inspection Service (FSIS), Agricultural Marketing Service (AMS), and Federal Grain Inspection Service (FGIS); and the National Marine Fisheries Service (NMFS), which is part of

[1]Seafood Inspection Issues, CRS Issue Brief, Congressional Research Service, Library of Congress (Order Code IB89126, Dec. 31, 1990).

the Department of Commerce. (See app. I for a summary of the laws and inspection activities of these five agencies.) Although seven other agencies have some responsibilities affecting food safety and quality, they generally do not perform safety inspections of food firms or products.[2] When jurisdictional authorities and/or responsibilities of federal agencies overlap, the Office of Management and Budget (OMB) is responsible for ensuring that the efforts of the respective federal agencies are effectively coordinated.

## Food and Drug Administration

FDA, under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended, is the federal agency primarily responsible for overseeing the safety of domestic and imported food products. FDA (1) regulates food production (except for meat, poultry, and some egg products) to ensure that food does not endanger the public health; (2) establishes standards of identity and quality for food products; and (3) reviews and approves food and color additives before foods containing them can be marketed. In addition, FDA enforces the act's prohibition against interstate commerce of adulterated foods and the false or misleading labeling of food products.

FDA primarily administers the FFDCA, which generally follows the regulatory approach of allowing food products to enter the market without preapproval by federal agencies. Therefore, FDA is not required to inspect foods or food firms on a given schedule. As a result, FDA inspects domestic food establishments on average once every 3 to 5 years. FDA inspects domestic establishments that manufacture, process, pack, or hold food to ensure compliance with federal laws, regulations, and good manufacturing practices.[3] FDA does not have jurisdiction over, and therefore does not inspect, foreign food establishments; however, FDA is responsible for inspecting and testing imported food products to ensure that the products meet the same safety and labeling standards as domestic foods. To supplement its own inspection efforts, FDA contracts with state agencies for some inspections.

In fiscal year 1991, FDA devoted 2,637 staff years—about 31 percent of its total staff year budget—to food safety activities, including overseeing the

[2]These agencies are the Environmental Protection Agency; the Department of Treasury's Bureau of Alcohol, Tobacco and Firearms and U.S. Customs Service; USDA's Animal and Plant Health Inspection Service and Agricultural Research Service; HHS' Centers for Disease Control; and the Federal Trade Commission. Our report entitled Food Safety and Quality: Who Does What in the Federal Government (GAO/RCED-91-19A&B, Dec. 21, 1990) contains additional information on the food safety roles of these agencies.

[3]Good manufacturing practices are processes for ensuring that food is safe and has been prepared, packed, and held under sanitary conditions.

estimated 53,000 domestic food establishments under its jurisdiction to ensure that they comply with federal laws and regulations and approving food additives and colorings. About 255 staff years were used to inspect about 9,200 domestic food establishments and another 7,630 domestic establishments were inspected through contracts with state agencies.

Generally, FDA food safety inspection activities are funded by federal appropriations. FDA does not charge or seek reimbursement for its inspections because it has no statutory authority to do so. Of the $690 million in total funds appropriated for FDA in fiscal year 1991, about $184 million, or 27 percent, was devoted to activities pertinent to food and food products.

## U.S. Department of Agriculture

Three USDA agencies have major food safety and quality responsibilities—FSIS, AMS, and FGIS. Generally, USDA agencies concerned with food safety require that products be approved before they enter the market. USDA agencies therefore often have greater authorities than FDA, including the preapproval of plant and equipment used in production. USDA agencies also operate as service agencies to industry by providing reimbursable grading services for meat, poultry, egg, dairy, fruit, nut, vegetable, and grain products. In these cases, the agencies also usually perform inspections to ensure that the products are produced under sanitary conditions before receiving a federal grade. The agencies have the following roles in food safety and quality:

### Food Safety and Inspection Service

FSIS oversees the slaughter and processing of meat and poultry sold in interstate commerce and inspects imported meat and poultry products to ensure that they are safe, wholesome, and properly labeled. Two laws—the meat and poultry acts—set out FSIS' basic meat and poultry inspection responsibilities. The meat act was the first food safety law to require that products be approved by the federal government before being marketed. The poultry act is very similar to the meat act.

The meat act regulates meat from cattle, swine, goats, sheep, and equines (horses); the poultry act defines poultry as domesticated fowl, which FSIS regulations define as chickens, turkeys, ducks, geese, and guineas. Other products that may commonly be considered meat or poultry, such as buffalo, venison, squab, quail, and pheasant, are not covered by the meat act or the poultry act. Although FSIS has voluntary inspection programs for these foods, they fall under FDA's jurisdiction.

As mandated by the two acts, slaughtering plants are under continuous FSIS inspection. If a federal inspector is not present, the animals cannot be slaughtered. FSIS inspects meat animals both before and after slaughter.

The acts also require FSIS inspectors to monitor processing plant operations, such as deboning and canning, to ensure that plants are sanitary and adhere to approved procedures and label specifications. The meat and poultry acts do not explicitly set inspection frequencies for meat- and poultry-processing plants. However, FSIS has interpreted the acts as requiring the daily inspection of meat- and poultry-processing plants and has established its regulations accordingly. That is, an FSIS inspector must visit each meat- and poultry-processing plant for an unspecified period of time—which may be as little as an hour—each operating day.

In fiscal year 1991, FSIS devoted over 9,000 staff years to overseeing about 6,100 meat and poultry plants—400 slaughtering plants, 1,070 combination plants performing both slaughtering and processing operations, and 4,630 processing plants. FSIS had about 7,350 in-plant inspectors, of whom about 960 were veterinarians.

FSIS activities are funded by federal appropriations and reimbursements. FSIS provides inspection services at no charge to industry on the basis of a 40-hour work week per inspector. Establishments that require FSIS inspectors to work more than 40 hours must reimburse FSIS for overtime costs. Of the $505 million in total funds available to FSIS in fiscal year 1991, federal appropriations made up about $449 million, and industry payments for overtime and voluntary inspection services made up about $56 million.

## Agricultural Marketing Service

Under the egg act, AMS has food safety responsibilities for eggs and egg products that are similar to FSIS' responsibility for meat and poultry.[4] As required by the egg act, AMS inspects egg-product-processing plants continuously. In addition, through cooperative agreements with state regulators, AMS inspects certain hatcheries and egg packers quarterly. In 1991, AMS spent about 35 staff years assisting in and overseeing the inspection of about 1,150 egg-packing plants and 475 hatcheries, and 179 staff years inspecting 82 egg-product plants that were under continuous inspection.

[4]Egg products are defined as any dried, frozen, or liquid eggs, whether or not the products contain other ingredients. Egg products do not, however, include products that contain eggs in a relatively small proportion (such as noodles) or products that historically have not been considered products of the egg industry (such as custards or omelets). Products that contain eggs but are exempt from inspection under the egg act are inspected by FDA.

AMS also facilitates the marketing of many agricultural commodities and products. Under the Agricultural Marketing Act of 1946, as amended, AMS develops quality standards for and, upon request, grades meat, poultry, egg, dairy, fruit, nut, and vegetable products. While this grading is a voluntary, reimbursable program for those wishing these services, AMS also performs in-plant sanitation inspections at the facilities to ensure that they are sanitary and that the products being graded are safe and wholesome. (AMS does not perform sanitation inspections in meat and poultry plants; these inspections are performed by FSIS personnel.) AMS sanitation inspections include daily sanitation reviews whenever grading is taking place as well as unannounced sanitation inspections at least twice a year in dairy plants and at least once a year in processed fruit and vegetable plants. Although participation in these programs is voluntary, firms have some incentive to participate. For example, any firm that wishes to sell food products to the federal government must typically have the products inspected and graded to ensure compliance with federal contract requirements.

In fiscal year 1991, about 2,100 permanent, full-time AMS employees provided grading and marketing services, approximately 1,100 of whom were inspection and grading personnel whose duties included inspecting food plant facilities. This work force was supplemented by hundreds of seasonal or intermittent workers and thousands of workers employed under cooperative agreements with state agencies. During that fiscal year, AMS had contracts for in-plant inspections at 650 dairy plants and 390 fruit, nut, and vegetable processing and packing plants. AMS also performs lot inspections—the inspection of specific loads, shipments, or batches—of processed fruits, nuts, and vegetables for about 3,200 firms.

AMS activities are funded through both appropriated funds and user fees. Federal appropriations pay for mandatory inspections under the egg act, but user fees paid by industry fund AMS' voluntary inspection and grading activities. In fiscal year 1991, AMS spent about $118 million on food safety and quality activities, about 20 percent from appropriated funds, and the balance from user fees for voluntary grading services.

## Federal Grain Inspection Service

FGIS' primary mission is to facilitate the marketing of grain, oilseeds, pulses (e.g., dry peas), rice, and related commodities, but it also has some food safety and quality responsibilities. The U.S. Grain Standards Act generally requires that FGIS inspect and weigh every grain shipment destined for export; since 1990, FGIS has also been required to test each corn shipment

for aflatoxin.[5] The act also created a voluntary domestic program for the inspection of grain. Similarly, the Agricultural Marketing Act of 1946 created a voluntary inspection and grading service administered by FGIS for grain and other products, such as rice and edible dry beans. Participation is generally required by contract for any firm that sells such products to the federal government.

Under its programs, FGIS (1) inspects grain for quality; (2) inspects corn, sorghum, wheat, rice, and processed grain products for aflatoxin; and (3) is developing a data base of chemical residues that, among other things, the Environmental Protection Agency could use when establishing limits for residues in grain. FGIS also frequently conducts sanitation inspections as part of its inspection and grading service. However, FGIS has no enforcement authority and therefore must refer instances of contaminated grain or grain products to FDA for follow-up.

FGIS activities are funded through appropriations and user fees. Federal appropriations fund FGIS' compliance and export-monitoring activities; user fees fund its inspection and weighing activities. In fiscal year 1991, FGIS devoted 580 staff years to grain inspection, including over 200 sanitation inspections of 75 to 100 plants. FGIS spent about $40 million on its compliance, weighing, and inspection activities, of which about $9.5 million came from appropriated funds and the balance of $30.5 million came from user fees.

## National Marine Fisheries Service

The Department of Commerce's NMFS, which is part of the National Oceanic and Atmospheric Administration, conducts a voluntary National Seafood Inspection Program. NMFS' voluntary, fee-based program, which provides grading and related inspection services for seafood products, is the largest federal government effort, in terms of staff years, directed at seafood safety and quality. However, seafood, unlike other major animal food products, comes under FDA's jurisdiction. Consequently, there is no requirement for federal inspection or approval of seafood products before marketing, although FDA significantly increased its oversight of seafood processors in fiscal years 1991 and 1992 by inspecting all domestic seafood processors.

NMFS evaluates the condition of seafood products for wholesomeness, proper labeling, and conformity with standards. NMFS also conducts a

[5]Aflatoxin is a potent natural toxin formed by two common molds. It forms on crops in the field or in storage and can cause illness or death when eaten in sufficient quantities.

sanitation inspection every day that it provides grading services in a ship or in a plant. When NMFS finds that a ship or plant does not comply with sanitation standards, it notifies the plant's management of the deficiencies it has identified. Although NMFS has no direct authority over the ship or plant, it may suspend grading services to provide an incentive for corrective action. When NMFS identifies potential safety or health concerns, it has to notify FDA or the responsible state agency if compliance is to be pursued through regulatory action.

In fiscal year 1991, NMFS devoted about 300 staff years to its seafood inspection program and had, on average, contracts with 230 seafood processors to conduct grading and inspection activities. NMFS' activities are funded through a combination of user fees and appropriated funds. Grading and inspection activities provided under the inspection program are funded by user fees; other activities, such as standards and specifications setting and most laboratory work, are funded by appropriations. For fiscal year 1991, NMFS funding for its grading and inspection activities, excluding research, totaled about $11.6 million in user fees and $1.2 million in federal appropriations.

## Office of Management and Budget

OMB assists in the development of efficient coordinating mechanisms to implement government activities and expand interagency cooperation. OMB, established as part of the Office of the President, is responsible for ensuring that agency programs are coordinated and that federal funds are expended in the most economical manner, with the least possible overlap and duplication of effort.

## State Agencies

In addition to federal oversight efforts, states have their own food safety and quality agencies, statutes, regulations, and inspection programs. States may inspect food establishments within their boundaries; states thus inspect some of the same firms inspected by the federal agencies.

## Objectives, Scope, and Methodology

Concerned about the effectiveness of the federal food safety system, the Chairman of the Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, asked us to determine if (1) food inspection systems are logical and consistent, (2) agencies are efficiently using federal resources for inspection, and (3) agencies are effectively coordinating their food safety and quality inspection efforts. In addition, we provided options for congressional consideration that involve

fundamental changes to food inspections designed to achieve a more uniform, health-based federal system.

To determine whether inspection systems are logical and consistent, we reviewed the laws, regulations, and policies pertaining to food safety and quality authorities and inspection responsibilities. We also reviewed previous studies and reports on federal food safety and quality inspection activities. (See app. II for a listing of food safety inspection studies and reports.) We met with representatives from industry and consumer groups as well as academicians to obtain their views on the structure of the federal food safety and quality inspection system. We also interviewed federal officials from each of the five major inspection agencies that oversee or provide grading services to the food-processing industry—FDA, FSIS, AMS, FGIS, and NMFS—to learn their views and concerns about their ability to fulfill their mission, given current authorities, responsibilities, and resources.

To determine whether agencies are using federal resources directed toward food safety inspections efficiently, we analyzed the frequency of agency inspections and compared inspection activities to identify whether inspection frequencies were based on risk and the extent to which they overlapped. We reviewed the inspection policies and procedures of FDA, FSIS, AMS, FGIS, and NMFS and, except for FGIS, analyzed their inspection records for the 3-1/2-year period from October 1, 1987, through March 31, 1991.[6] We also interviewed federal and state agency officials responsible for food safety and quality in six judgmentally selected states—California, Florida, Illinois, Pennsylvania, Texas, and Wisconsin. The six states were selected on the basis of the presence in the state of specific food industries or the number of establishments that had contracted for voluntary federal inspection and grading services.

To determine whether agencies are effectively coordinating their food safety and quality inspection efforts, we reviewed coordinating agreements made among the five principal food safety and quality agencies and interviewed officials responsible for implementing the agreements. For all five agencies, we requested, analyzed, and tracked notifications of food safety problems made to other agencies from January 1990 through November 1991 and analyzed the agencies' inspection records to identify instances when these kinds of notifications should have been made. We

[6]Although we reviewed FGIS' inspection policies and procedures, we excluded FGIS from our analysis of efficiency because FGIS inspections are frequently performed as a part of purchase contracts with government agencies. In these cases, inspection policies and procedures are dictated by the purchasing agency, not by FGIS.

also tracked 34 randomly selected referrals that the grading agencies made to FDA to determine if they were promptly investigated.

We conducted this review between March 1991 and April 1992 in accordance with generally accepted government auditing standards. We discussed the facts presented and general conclusions drawn in our draft report with responsible officials of the five major food safety and quality inspection agencies and OMB. We made technical changes where appropriate. However, as requested, we did not obtain written comments on this report.

# Diverse Regulatory Approaches Result in Inconsistent Oversight

The food safety laws administered by FDA, FSIS, and AMS provide the agencies with different authorities and responsibilities, reflecting significantly different regulatory approaches. Plants producing foods under FSIS' jurisdiction are inspected at least daily, yet processors of foods posing similar risk, but under FDA's jurisdiction, are inspected on average once every 3 to 5 years. In addition, over the years, ambiguities in the law and changes in the food industry have forced agencies to decide which specific foods were subject to which laws. These decisions, however, have frequently been based not on the risks that such foods pose but on other considerations, such as the level of agency resources. Also, FSIS and, in some instances, AMS, have authorities not available to FDA, such as the ability to require firms to register or the ability to detain adulterated foods. These inconsistencies reduce the effectiveness of the federal food safety system and increase the likelihood that unsafe foods will enter the marketplace.

## Inspection Resource Allocation Should Be Based on Health Risk

The purpose of the federal food safety inspection system is to protect the public from health risks associated with food-borne hazards. Limited federal resources and the impracticality of the continuous inspection of food establishments dictates that federal inspection agencies effectively allocate inspection resources. The work of our office and others generally has been consistent in identifying risk assessment as an essential principle of an efficient and effective inspection program necessary for protecting public health.

Risk assessment is based on the concept that the frequency and intensity of inspection coverage should be varied in accordance with food safety risks, such as the potential contamination associated with the commodity (e.g., the potential for pathogenic microorganisms, chemical residues, or spoilage); the processing operation (e.g., canning, freezing, cooking, or cutting and repacking); and the plant's quality control procedures and history of compliance with regulatory requirements (e.g., good manufacturing practices and sanitation standards). For example, according to the National Academy of Sciences, one of the characteristics of an optimal inspection system is one with different levels of intensity, reflecting the degree of public health risk at various stages in the process, the reliability of the monitoring system, the compliance history of the processing plant, and the special needs of the intended consumer.

## Frequency of Inspection Differs for Foods Posing Similar Risk

Many food products that pose a similar health risk to the consumer are subject to significantly different frequencies of inspection, depending on which law and thus which regulatory approach they are governed by. Because of the preapproval approach of the meat and poultry acts, food establishments regulated by FSIS are inspected continuously or daily, depending on the type of operation. In contrast, foods governed by FDA's basic law are not subject to preapproval and their processors do not undergo daily or continuous inspection. In fact, most food firms under FDA's jurisdiction are inspected on average about once every 3 to 5 years. Furthermore, these FDA inspections are not designed to approve food products but are instead a check to ensure that plants are following FDA's criteria for good manufacturing practices. Inspections are thus not necessarily based on the risk posed, but on the regulatory approach behind the governing law. As a result, some foods may be receiving too much attention—especially considering the limited level of federal resources available for food safety—while other foods may not be receiving enough attention.

## Governing Laws Are Inconsistent

In some cases, the inconsistent regulation and inspection of certain foods are derived directly from the law. For example, the meat act regulates meat from cattle, swine, goats, sheep, and equines (horses), thus requiring that federal inspectors be continuously present during slaughter or visit the processing facility on a daily basis to approve these products. In contrast, meat products regulated by the FFDCA, such as venison, buffalo, and rabbit, are under FDA's jurisdiction and therefore not subject to such requirements. The case is similar for poultry, which federal law and agency regulations define as chickens, turkeys, ducks, geese, and guineas but not quail, pheasant, and squab—which are not covered by the poultry act but by the FFDCA.

While this distinction may have been of little importance when the meat act was passed in 1907, changes in consumer preference and consumption of leaner, lower-cholesterol products like buffalo and venison have increased significantly. For example, industry data show that about 1.4 million pounds of venison was sold to U.S. restaurants and retailers in 1990, an increase of over 60 percent since 1986. According to an industry official, in one state alone, about 100 ranchers are raising venison for food, and the numbers are growing rapidly. Similarly, between 1986 and 1991 the number of buffalo slaughtered for food doubled from about 6,000 to 12,000. To meet the growing demand, production is evolving into high-volume farming operations posing risks similar to those encountered

with traditional cattle and poultry farms, such as diseases, drug residues, and other contaminants. As production and consumption of some of these alternative meat and poultry products increases, the potential health risk from consuming contaminated products could also increase.

FDA and FSIS officials agree that there is virtually no difference in the health risk posed by meat and poultry slaughtering operations inspected by FSIS and those inspected by FDA. They believed that all animal products should be treated consistently in accordance with the health risk that those products pose to the public. FSIS officials also said that most states do not inspect these alternative products because the states do not have mandatory inspection programs for them. For example, only two of the six states we visited provided inspection coverage of all plants slaughtering these alternative products.

The situation is similar for seafood, which is the only major animal product not covered by some form of mandatory—that is, continuous or daily—inspection and preapproval program. Seafood consumption grew rapidly during the early 1980s but has stagnated since we last reported on seafood problems in 1988.[1] Seafood consumption increased from 12.5 pounds per person in 1980 to a high of 16.2 pounds per person in 1987, then dropped to 15.2 pounds per person in 1988 and has remained relatively constant since then. The executive vice president of the National Fisheries Institute, which represents about 30 percent of the U.S. seafood industry, has called for a mandatory seafood inspection program to bolster falling consumer confidence attributed to disclosures of contaminated seafood products.

A growing recognition since about 1990 of the potential safety risk of eating fish and shellfish has led to the introduction of several seafood safety bills in the Congress. Although none of these measures have passed as yet, debate has been intense on the need for such legislation. In addition, FDA received additional funding to increase its inspections of seafood-processing operations beginning in fiscal year 1991. While FDA's inspections have increased under this initiative, the number of planned inspections is still low—about one a year per processing plant. According to a 1991 report of the Institute of Medicine on seafood safety, ". . . the present monitoring and inspection program carried out by all federal agencies lacks both the frequency and the direction sufficient to ensure

[1]Seafood Safety: Seriousness of Problems and Efforts to Protect Consumers (GAO/RCED-88-135, Aug. 10, 1988).

effective implementation of the nation's regulatory limits for seafood safety."[2]

## Administrative Decisions Promote Inconsistencies

Federal statutes generally specify the categories of meat, poultry, and eggs that are regulated by and thus subject to inspection by FSIS and AMS. Over the years, ambiguities in the law and changes in the food industry have resulted in FSIS' and AMS' having to decide which specific foods were subject to which laws. The decisions, however, have frequently been based not on the risks that such foods pose but on other considerations.

In some instances, jurisdictional decisions have been based merely on the proportion of meat or poultry that the food contains. Jurisdiction over hybrid animals, for example, has been determined on the basis of the proportion of the FSIS-inspected species in the hybrid. FSIS inspects beefalo, a hybrid of cattle and buffalo that contains more than 50 percent cattle, yet FDA inspects a similar hybrid, cattalo, which contains no more than 50 percent cattle. Similarly, the regulation of some processed products, such as soups and spaghetti sauces, depends on the level of their meat or poultry content. FSIS inspects establishments that process products containing, by weight, at least 2 percent cooked meat or poultry or 3 percent fresh meat or poultry. On the other hand, FDA inspects establishments whose products contain meat or poultry in lesser amounts.

An example of the problems that can occur when administrative decisions are based solely on the proportion of meat or poultry contained in a product was reported by USDA's Inspector General in June 1990. The Inspector General found that FSIS had established minimum cooking temperatures for products containing poultry to ensure that salmonella bacteria—which frequently cause food poisoning—were killed during processing, but FSIS' policy did not ensure consumer safety because only products containing more than 50 percent poultry had to comply with the standards. For example, one product containing 51 percent beef and 49 percent poultry was cooked to only 130 degrees Fahrenheit, or 30 degrees under the temperature necessary to kill salmonella. Had the percentage of beef and poultry been reversed, FSIS would have required a cooking temperature of 160 degrees. According to the report, FSIS personnel could not provide any assurance that there was any difference in risk between a product containing 51 percent poultry and one containing 49 percent.

[2]Seafood Safety, Committee on the Evaluation of the Safety of Fish Products, Institute of Medicine, National Academy of Sciences (1991). The Institute of Medicine, chartered in 1970 by the National Academy of Sciences, examines policy matters concerning public health. The Institute's 1991 report was commissioned by the U.S. Department of Commerce.

In other instances, decisions on regulatory jurisdiction are based on whether the food has historically been considered a product of the meat, poultry, or egg industry. FSIS inspects establishments that process open-face meat or poultry sandwiches (e.g., those with one slice of bread), but FDA inspects closed-face or traditional meat or poultry sandwiches (e.g., those with two slices of bread), which FSIS does not consider part of the meat or poultry industry. Furthermore, AMS inspects eggs in the shell as well as liquid, frozen, and dried eggs, while FDA inspects eggnog mixes, french toast, and sandwiches containing eggs because they are not considered part of the egg industry.

An agency's resource limitations may also determine whether a product is under the jurisdiction of FSIS or FDA. For example, the decision on the inspection of meat and poultry sandwiches was made, at least in part, because of resource constraints. Under its basic legislation, FSIS would have to inspect every meat and poultry sandwich processor daily to conform with the preapproval approach espoused by the meat and poultry laws. According to FSIS officials, FSIS lacked the resources to inspect all meat or poultry sandwich processors, so it decided to inspect the less common open-face sandwich, while leaving inspections of other sandwiches to FDA. In fiscal year 1991, FDA devoted about 255 staff years to inspect domestic food firms under its jurisdiction, while FSIS used over 9,000 staff years to oversee fewer firms. As a result, processors of traditional sandwiches are unlikely to be inspected more often than once every 3 to 5 years by FDA, while processors of open-face meat and poultry sandwiches are inspected daily. FDA and USDA officials said that there is no difference in the risk posed by these products.

These administrative decisions on jurisdictions have resulted in widely differing inspection frequencies for products with the same or similar risks, as shown in table 2.1.

**Table 2.1: Differences in Inspection Frequency Resulting From Jurisdictional Decisions**

| Plant inspected daily by FSIS | Plant inspected about once every 3-5 years by FDA |
|---|---|
| Open-face sandwiches | Traditional sandwiches |
| Hot dog in a pastry dough | Hot dog in a roll |
| Corn dog | Bagel dog |
| Dehydrated chicken soup | Dehydrated beef soup |
| Beef broth | Chicken broth |
| Spaghetti sauce with meat stock | Spaghetti sauce without meat stock |
| Beans with bacon (2 percent or more bacon) | Pork and beans—no limit on amount of pork specified |
| Pizza with meat topping | Pizza without meat topping |
| Soups with more than 2 percent meat or poultry | Soups with less than 2 percent meat or poultry |

Besides the variation in the frequency of inspection for foods posing similar risks shown in table 2.1, inspection of the foods can be internally inconsistent and illogical, as figure 2.1 shows.

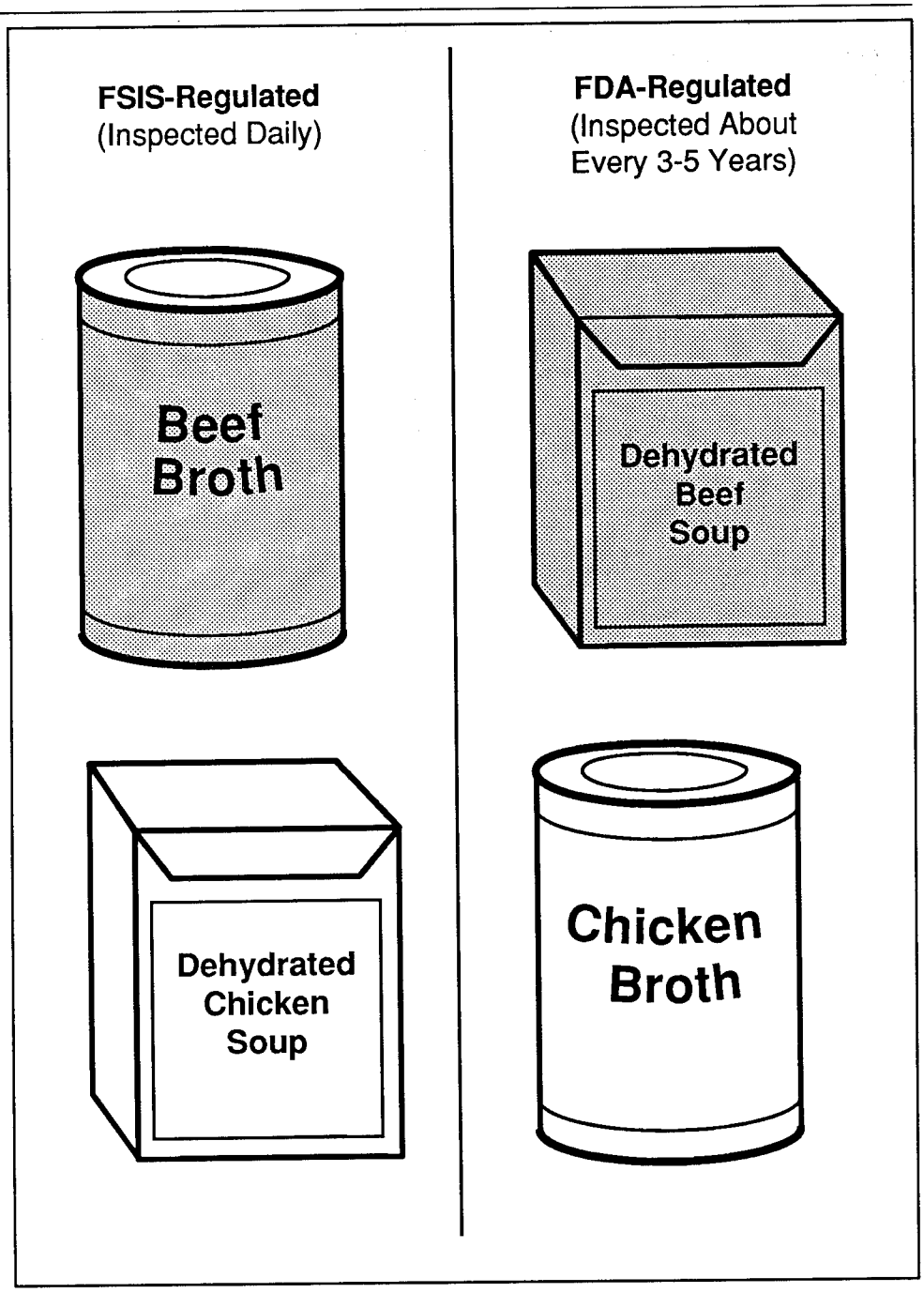


**Figure 2.1: Inconsistent and Illogical Treatment of Foods Posing Similar Risks**

These differences in the regulatory treatment of canned products cannot be justified on the basis of differences in risk. According to leading food safety researchers from the Food Research Institute of the University of Wisconsin and food safety officials of FSIS and state regulatory agencies, the canning process itself, not the amount of meat in the product, poses the greatest food safety risk because of the potential for botulism. Both meat and nonmeat products can cause botulism-related disease if the canning process is faulty. One researcher added that, in his opinion, federal attention to specific food products is based more on compliance with specific laws and the resources available to regulatory agencies than on the risk to the consumer.

## Inconsistent Enforcement Authorities Can Hinder Agency Food Safety Efforts

The different regulatory approaches of the basic food safety laws that federal agencies follow have also created differences in the enforcement authorities granted to the agencies. In contrast to USDA, FDA generally cannot (1) presume that firms are engaged in interstate commerce, (2) require food processors to register, (3) prohibit use of equipment that may contaminate food, and (4) detain domestic products that violate food safety standards.

Some of these differences result directly from the applicable laws while others are derived indirectly from the laws. For example, while the law gives USDA clear rights to examine company records pertinent to the safety of food products, it does not grant USDA authority to preapprove a processor's plant and equipment. However, USDA has essentially assumed that authority by refusing to provide inspection services to plants that have not agreed to let the Department review their plant and equipment. Under the law, a meat or poultry plant cannot operate without USDA inspectors. FDA has no such rights or leverage. In fact, plants under FDA's jurisdiction do not even have to notify FDA that they are in business. FDA has sought increased enforcement authority to ensure food safety, but HHS and OMB have not forwarded FDA's legislative proposals to the Congress for consideration. The lack of enforcement authority can inhibit FDA's ability to oversee food processors and ensure a safe, high-quality food supply.

### Need to Verify Interstate Commerce Hinders FDA's Oversight

The jurisdiction of both USDA and FDA is restricted primarily to firms operating in interstate commerce. However, under USDA's basic laws, most firms producing products that the Department regulates are presumed to be operating in interstate commerce, precluding the need for USDA to prove its jurisdiction. In contrast, FDA must verify that establishments are

involved in interstate commerce and thus subject to its actions. Because some firms may force FDA to prove in court that they are operating in interstate commerce, FDA's ability to oversee domestic food processing is hindered. FDA can also be required to prove that firms are involved in interstate commerce when requesting a court order to seize adulterated products.

In our September 1984 report on FDA's enforcement authority,[3] we pointed out that uncooperative firms sometimes forced FDA to undertake the time-consuming documentation of interstate shipments of foods before the agency could obtain a court order to detain or seize adulterated food products. We also noted that such detentions or seizures were sometimes delayed or prevented when firms refused FDA access to shipping records needed to prove that the firms were involved in interstate commerce.

In March 1991, FDA's Commissioner testified that new enforcement tools, including the authority to inspect records and to presume that firms were operating in interstate commerce, were among his highest priorities for improving FDA's food safety oversight.[4] Subsequently, H.R. 2597 was introduced on June 7, 1991. Among other things, this legislation would give FDA the authority to inspect records and extend its authority by amending the definition of interstate commerce. In effect, the amendment would eliminate the need for FDA to prove that a firm is involved in interstate commerce before the agency could inspect or obtain a court order to seize the firm's products.

Objections to giving FDA such authority, however, have been expressed by 23 trade associations representing the food and drug industry. In a June 21, 1991, letter to Representative Henry A. Waxman objecting to H.R. 2597, these trade associations argued that a case had not been adequately made that FDA needs increased enforcement powers. However, according to a 1991 congressional subcommittee report on FDA's regulatory authority, FDA spends between 25 and 30 staff years annually, which we estimate costs

[3]Legislative Changes and Administrative Improvements Should Be Considered for FDA to Better Protect the Public From Adulterated Food Products (GAO/HRD-84-61, Sept. 26, 1984). In this report we said that the Congress should consider amending the FFDCA to authorize FDA to detain food products suspected of being adulterated and to review firms' production and distribution records of adulterated products. We also said that the Congress should consider increasing the maximum fine associated with criminal prosecutions for persons or firms convicted of violating provisions of the act.

[4]Hearings before the Subcommittee on Health and the Environment, House Committee on Energy and Commerce, Mar. 13, 1991, transcript pp. 50 and 51.

about $1.9 million, on documenting interstate commerce for the foods, drugs, and devices that it regulates.[5]

## Firms Under FDA's Jurisdiction Are Not Required to Register

Food establishments are generally not required to register with FDA, with the exception of firms that produce low-acid or acidified canned foods or infant formula. Special regulations for low-acid and acidified canned food were first adopted by FDA in 1973 because of illnesses and deaths attributed to botulism resulting from lax practices in the canning plants that produce these products. As a result, all commercial processors of these canned foods are required to register and file processing information with the FDA. Similarly, the Infant Formula Act of 1980, amending the FFDCA, resulted in increased FDA regulatory authority over manufacturers of infant formula, including a requirement that they register.

Firms under FSIS' and AMS' jurisdiction—since they need these agencies' inspection services to operate—must register with the agencies. Furthermore, as discussed earlier, the firms must obtain the agencies' approval of their plant, equipment, and operating procedures. Consequently, FSIS and AMS are in a better position to identify all food plants under their jurisdiction. Without a similar requirement, FDA's ability to identify all food processors under its jurisdiction is limited. As a result, FDA is not aware of, and therefore does not oversee and inspect, some domestic food establishments.

For example, FDA was not aware of specific food plants under its jurisdiction in the following instances:

- A buffalo-meat-processing plant established in 1981 was not inspected until 1991, when FDA first learned of the plant's existence.
- A deer-slaughtering plant established about 9 years ago has never been inspected by FDA because FDA did not know about the plant.
- According to an FDA inspector responsible for inspecting seafood plants in Maryland, Virginia, West Virginia, and the District of Columbia, he and his staff had to contact local grocers and look through telephone books in an attempt to find seafood processors in their area to meet FDA's 1991 initiative to inspect all domestic seafood establishments under FDA's jurisdiction.

[5]Filthy Food, Dubious Drugs, and Defective Devices: The Legacy of FDA's Antiquated Statute, staff report of the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce, (1991).

- In our February 1992 report on bottled water,[6] we reported that although FDA's plant inventory listed about 410 domestic bottled water plants in 1990, FDA officials estimated that about 475 bottled water plants were actually involved in interstate commerce.

HHS' Inspector General also noted the same problem in an August 1991 report. According to that report, 17 of FDA's 21 district office directors believe the identification of food firms could be improved.[7] The Inspector General's report recommended, among other things, that FDA design a uniform registration system to ensure the identification of all food firms under its jurisdiction.

According to FDA officials, the agency lacks the resources needed to operate such a national registration program. However, it is not clear that the resources required to operate a registration system would substantially exceed those that FDA currently uses to identify food establishments under its jurisdiction. For example, FDA now expends extensive effort and resources to identify plants under its jurisdictions by reviewing newspapers, magazines, phone books, industry publications, trade periodicals, surveillance reports, and consumer complaints. FDA district offices also rely on information from states to identify food firms.

It is important that FDA have a means to identify all plants under its jurisdiction in order to provide better assurance that every food processor is periodically inspected. A national registration system, based on a simple requirement that processors operating in interstate commerce notify FDA when they initiate operations, could provide such identification.

FDA's parent organization, the Public Health Service, is asking in its 1993 legislative proposal that FDA be provided with discretionary authority to require the registration of all establishments that engage in activities subject to FDA regulation. The proposal states, in part, that the most immediate needs are to require the registration of domestic and foreign food manufacturers, packers and distributors, and import brokers, since registering these businesses would enhance FDA's efforts to expand coverage of high-risk foods and unproven technologies.

We discussed such a registration system with two trade associations that represent the processed foods industry. One association told us that it

[6]Food Safety and Quality: Limitations of FDA's Bottled Water Survey and Options for Better Oversight (GAO/RCED-92-87, Feb. 10, 1992).

[7]FDA Food Safety Inspection (OEI-05-90-01070, Aug. 1991).

basically has no objection to a registration system as long as there would be no cost to the industry. The second association, while not taking a formal position on the issue, was concerned about the government's ability to handle all the paperwork, given the large number of food processors. Both associations also questioned the effectiveness of such a system, because they believed that some firms about which the government would have food safety concerns would probably not register and instead take the risk of being discovered.

A simple registration system based on a requirement that processors operating in interstate commerce notify FDA when they begin operations would cost the industry little. Furthermore, appropriate penalties would likely discourage any potential failure to register.

## Authority to Prevent Use of Potentially Unsafe Equipment Is Inconsistent

FDA and USDA agencies do not generally have the same authorities to prevent the use of unsafe plants, equipment, or processes. Although the law does not explicitly give USDA such authority, the Department has assumed this authority by virtue of its ability to grant or withhold inspection services to plants under its jurisdiction. Without USDA's inspection services, plants cannot market their products. Essentially, USDA has taken the position that plants must be designed and built to process food in a safe manner. USDA has thus been able to require plants to submit documentation on their designs, equipment, and processing operations to USDA for its approval before they produce meat or poultry products. Since FDA does not preapprove food products under its jurisdiction, its ability to exercise such authority is limited. According to FDA officials, FDA, under its injunction authority, can prohibit a firm from using specific pieces of equipment if it demonstrates that use of the equipment can lead to contaminated products. As a result, equipment that can be prohibited by FSIS and AMS across-the-board must be prohibited by FDA on a plant-by-plant, case-by-case basis.

For example, firms producing liquid, frozen, and dried eggs, which are inspected by AMS, are prohibited from using centrifugal egg-breaking machines because of the risk of bacterial contamination. These machines break a large quantity of eggs at one time in a rotating drum and, by centrifugal force, push the liquid egg out through holes in the drum, thus separating the liquid eggs from the shells. AMS prohibits the use of these machines because the liquid eggs are mixed with the shells before they are separated. According to AMS officials, this contact almost guarantees salmonella contamination, even though the egg pasteurization or drying

process kills the salmonella bacteria. A number of states have also banned or are in the process of banning the use of centrifugal egg-breaking machines.

In contrast, firms regulated by FDA that use shell eggs—which are not pasteurized or dried—in their production processes are allowed to use centrifugal breaking machines. These firms include bakeries, which may produce products, such as meringues and pound cake, containing lightly cooked eggs, which pose more serious health risks than products produced by firms under AMS' jurisdiction. Risks occur because these lightly cooked products do not reach high enough temperatures to kill the salmonella bacteria.

According to an HHS associate chief counsel for foods, FDA lacks clear authority to prohibit the use of or require the approval of processing equipment, and any attempt to impose such a requirement would likely be challenged by industry. Therefore, FDA's policy is to take action against foods produced under unsanitary conditions or otherwise found to violate standards. Such actions can, in turn, lead firms to decide to replace inappropriate equipment. However, FDA must obtain a court order before it can seize such products.

Both trade associations we contacted believed that FDA already has sufficient authority to ban equipment if it can be proven that the equipment results in an adulterated product. Both associations believe, moreover, that before any equipment is banned, the burden of proof should continue to be with the government to prove that continued use of the equipment puts the consumer at risk.

## Authority to Prevent Unsafe Products From Reaching the Market Is Inconsistent

The ability of FDA and USDA to prevent contaminated products from reaching the market is also inconsistent. FDA, which does not preapprove foods, cannot prevent a contaminated domestic product from reaching the market without a court order. Furthermore, once a contaminated product reaches the market and FDA becomes aware of it, FDA cannot automatically detain it from further distribution without either obtaining the firm's voluntary cooperation or obtaining a court order. As discussed earlier, FDA may even have to prove that the firm is engaged in interstate commerce and that FDA has jurisdiction over the product.

The FFDCA does not give FDA the authority to prohibit the movement or marketing of adulterated domestic food products while it processes

seizure actions through the U.S. attorney's office and the courts. As a result, FDA must detain adulterated food products by getting a federal court order for seizure, enlisting the cooperation of numerous states that have the authority to detain adulterated products, or convincing the firms involved to voluntarily hold food products while such actions are being processed. While FDA is obtaining a court order for seizure, however, potentially dangerous foods can be shipped and sold to consumers.

In contrast, FSIS and AMS have the authority to temporarily hold suspect foods while they seek court orders for seizure. The agencies can detain products for up to 20 days without a court order. This detention authority is important because not all food establishments cooperate with federal agencies by holding suspect foods.

FDA officials cited a recent example in which a firm continued to distribute a contaminated product for weeks while FDA and the firm negotiated the terms of a voluntary detention agreement. Testifying before the Subcommittee on Health and the Environment, House Committee on Energy and Commerce, in July 1991,[8] the Director of FDA's Northeast Region said that a decision to prevent the further distribution of distilled water, which was labeled for use in the preparation of infant formula but contaminated with isopropyl alcohol, was delayed for over 5 weeks.

FDA's need for detention authority has been repeatedly noted. Our 1984 report on FDA's enforcement authority said that FDA could not rely on states to detain adulterated food products, nor could FDA count on food companies to voluntarily hold adulterated products. In some cases, states disagree with FDA that the product is adulterated and should be seized. We reported that in 19 of 76 instances in which firms agreed to hold products in response to FDA's request, the firms distributed or sold all or part of the food before a court-ordered detention and seizure action was obtained. We recommended that the Congress consider amending the FFDCA to provide FDA with authority to detain products.

The previously cited HHS Inspector General's 1991 report on food safety inspections by the FDA also concluded that FDA's lack of immediate detention authority can allow adulterated foods to enter the marketplace. The report recommended that FDA seek authority allowing it to immediately detain products suspected of adulteration.

[8]Hearings on H.R. 2597 before the Subcommittee on Health and the Environment, House Committee on Energy and Commerce, July 17, 1991, transcript pp. 25 and 26.

The two trade associations representing the processed foods industry that we consulted were concerned that granting FDA such authority could result in potential abuse through arbitrary or unjustified detention. In their view, FDA already has sufficient authority when it is warranted. One association cited the threat of negative publicity as a powerful tool that FDA can use to force industry compliance, if necessary. Both associations believed, however, that detention authority could probably be made more acceptable to industry by providing certain safeguards and limitations. For example, the government could be held financially liable for unjustified detentions, and detention could be limited to safety problems.

## Conclusions

The division of responsibility for food safety between USDA and FDA has resulted in uneven regulatory treatment in the food industry, reducing the effectiveness of federal food inspection efforts. Food products and processes that pose similar risks to the consumer are treated differently because they fall under different agencies' jurisdictions. Thus, alternative poultry and meats, such as pheasant, buffalo, and venison, that are finding growing markets in the United States are currently slaughtered with little federal inspection. Consistent treatment of products posing similar risk could help decrease the likelihood that unsafe foods will enter the marketplace.

Differences in enforcement authorities among agencies also prevent consistent responses to similar risks to public health. Among the several authorities available to USDA but denied to FDA is the authority to require firms under its jurisdiction to register. A uniform national registration system would allow FDA to identify all the firms under its jurisdiction and ensure that the appropriate inspections took place. Similarly, FDA's lack of immediate detention authority when adulterated foods are found impairs the agency's ability to guarantee a safe food supply. In the past, FDA's food safety authority has been expanded in response to serious public health emergencies. Granting FDA authority similar to USDA's to detain contaminated products while legal remedies are pursued could help ensure the right of consumers to expect a safe food supply.

## Matters for Congressional Consideration

To provide consistent coverage of foods that pose similar risks, the Congress may wish to consider amending the meat and poultry acts to include alternative meat and poultry products whose consumption has been increasing and that pose health risks similar to those products traditionally covered by the acts.

Furthermore, to provide the federal regulatory agencies with the authorities they need to ensure a safe, high-quality food supply and to prevent unsafe food products from reaching U.S. consumers, the Congress may wish to consider providing FDA with enforcement authority that is consistent with that of other food safety agencies, such as FSIS.

# Federal Food Inspection Resources Are Not Efficiently Used

Federal agencies responsible for food safety and quality inspections are not using their resources efficiently. Although FSIS has the legal authority to inspect meat and poultry processors on the basis of the risk that their products pose, the agency still inspects these processors daily. Therefore, many establishments may be inspected more frequently and others less frequently than necessary, especially when compared with other food-processing establishments whose products present similar safety risks. Furthermore, because different federal agencies have safety or quality responsibilities for the same food commodities or products, some food processors may be inspected by two agencies on the same day, while other processors are not inspected for years. Although the agencies may have different roles, almost all of their inspections cover the same areas, primarily sanitation. As a result, federal food inspections may be duplicative.

## Daily Inspection of Processed Meat and Poultry Products Is Not Efficient

The federal meat and poultry inspection acts, as discussed in chapter 1, set out inspection requirements for meat and poultry establishments. As enacted, the acts required continuous inspection of meat and poultry slaughtering establishments and, as interpreted by FSIS, daily inspection of meat- and poultry-processing establishments.

To redirect FSIS inspections toward firms and food processes that pose the greatest risk, the Congress passed the Processed Products Inspection Improvement Act of 1986, which amended the requirements on inspection frequency for meat- and poultry-processing plants. For the 6-year period ending November 10, 1992, the act authorized FSIS to use its own discretion to determine the frequency of inspection, taking into account factors affecting the health risk of the product, including the nature of the processor's operations, the adequacy of processing controls and sanitary procedures, and the processor's history of compliance with regulatory requirements. The Congress expressed its intention, as set forth in section 407 of the act, to evaluate the amendment after the 6-year period to determine whether it should be extended or modified.

Three FSIS pilot tests in 1987 and 1988 subsequently demonstrated, according to FSIS, that discretionary inspection authority—that is, allowing the agency to exercise its judgment about how frequently inspection was necessary—showed potential for permitting the allocation of agency inspection resources to firms and processes where they were most needed. The agency concluded that discretionary inspection was worth testing on a nationwide basis. However, in May 1989 FSIS withdrew

proposed regulations published by the agency because they met with strong opposition. For example:

- The food-processing industry expressed concern that FSIS would place burdensome requirements on inspected establishments or shut down processing operations for extended periods. For example, FSIS could shut down a processing line because of unsanitary conditions but not return to reinspect the line for several days, even after the line had been immediately cleaned and sanitized.
- Consumers and some FSIS inspectors expressed concern that FSIS would use its new authority to reduce inspections and, consequently, reduce the safety and wholesomeness of processed meat and poultry products.

In withdrawing the proposed regulations, FSIS stated that it would gather additional information regarding a processing inspection system and would thereafter determine if a new proposal would be published. In March 1992, FSIS' newly appointed Administrator told us that the agency had no plans to implement discretionary inspection before the authority expired in November 1992. The Administrator indicated that he would support legislation extending FSIS' authority for discretionary inspection, although he was uncertain about how he might implement discretionary inspection.

Discretionary inspection would not, however, change federal regulatory requirements designed to ensure safe meat and poultry products. Only the frequency at which FSIS inspects the firms to ensure compliance with these requirements would change. Furthermore, if FSIS shut down a processing operation for food safety reasons, an inspection could be scheduled to immediately follow the plant's corrective actions. Discretionary inspections can also provide further incentive for plants to take the initiative to build safety and quality into routine operations rather than waiting for inspectors to identify problems and being forced to correct them after the fact.

Moreover, FSIS' current requirements mean that firms engaged in relatively simple cutting and packaging operations, with adequate and reliable processing and sanitation controls and good compliance histories, will continue to be inspected daily. Under discretionary inspection, FSIS would have an opportunity to redirect resources to higher risk operations or firms that do not meet these conditions.

In addition to allowing FSIS to redirect its inspection resources, discretionary inspection also has the potential to reduce costs. FSIS estimated in its fiscal year 1990 budget justification that 148 inspection staff years, costing an estimated $4.6 million annually, could be saved or redirected through discretionary inspections. These yearly savings are possible because discretionary inspection authority allows for staffing flexibility so that the frequency of inspection can be tailored to the needs of individual plants—periodic unannounced inspections for simple, low-risk operations, for example, rather than daily inspections.

A September 1986 report by USDA's Inspector General on FSIS' inspection program found that 615 staff years, or almost 30 percent of the agency's inspection resources (an amount more than double FDA's current domestic food safety inspection force), were devoted to inspecting small, simple processing operations, such as cutting, grinding, and repackaging of previously inspected products.[1] These operations are similar to those of retail butchers and supermarkets, which are not federally inspected. The Inspector General's report concluded that the cost of daily inspection may far outweigh its consumer benefits and using scarce federal inspection resources in this manner draws resources away from other areas that may need greater coverage because they present a higher risk potential. The report recommended that FSIS consider an inspection system based on the risk posed by the operation of individual meat- and poultry-processing plants.

However, because the federal agencies operate under different laws and appropriations, resources saved through discretionary inspection could not be immediately redirected to processors that have traditionally been exempt from FSIS inspection, such as processors of venison, buffalo, squab, and pheasant, and other infrequently inspected processors that are currently under FDA's jurisdiction, such as those making traditional meat sandwiches.

FSIS also devotes resources to the daily inspection of processors of products that contain small proportions (as low as 2 to 3 percent) of meat or poultry, such as canned soups, while FDA inspects canners of nonmeat/nonpoultry products on average once every few years. According to food safety experts as well as federal and state officials responsible for food safety activities, the frequency of inspection should be based on the risk posed by the product and not on which agency has jurisdiction. As

[1]Food Safety and Inspection Service: Meat and Poultry Inspection Program (Audit Report No. 38607-1-At, Sept. 26, 1986).

noted in chapter 2, the canning process itself, rather than the presence or lack of meat or poultry in canned products, poses the greatest food safety risk because of the potential for botulism.

According to a leading food safety researcher from the Food Research Institute of the University of Wisconsin, it would make more sense to base inspection frequencies on characteristics of the plant rather than product ingredients, such as meat. In his view, large soup-canning operations generally have high quality standards and procedures, while smaller establishments may put consumers at greater risk because their quality control measures may be less stringent.

Federal and state officials voiced similar opinions. An FSIS official responsible for standards and labels said that soup with meat, regulated by FSIS, and soup without meat, regulated by FDA, undergo the same canning process. He said that daily FSIS inspection of plants that can soups containing meat is unnecessary because soups with meat do not necessarily pose a greater health threat than soups without meat. A state official concurred that the frequency of inspection should be based on a risk analysis of the product and processes of the individual plant.

Previous studies have also concluded that discretionary inspection allows more efficient use of limited federal inspection resources. Our December 1977 report on FSIS' inspection program said that inspection resources could be used more efficiently and effectively if processing plant inspection frequencies were tailored to the inspection needs of individual plants.[2] We concluded that periodic unannounced inspections, instead of daily inspections, could be used to ensure the safety of meat and poultry, especially at plants with simple operations and good compliance with regulations. We recommended that the Secretary of Agriculture develop criteria for deciding the optimal frequency of inspection for individual processing plants.

The previously mentioned September 1986 USDA Inspector General report on FSIS' inspection program reached a similar conclusion. The report stated that the daily inspection requirement for meat-and poultry-processing plants limited FSIS' ability to maximize the efficiency and effectiveness of its inspection efforts. The report concluded that, with a risk-based approach to the inspection process, FSIS could maintain or

[2]A Better Way for the Department of Agriculture to Inspect Meat and Poultry Processing Plants (GAO/CED-78-11, Dec. 9, 1977).

increase the current level of consumer protection and be in a better position to effectively respond to potential budget reductions.

## Federal Inspection Efforts Overlap

The inspection of food establishments by more than one federal agency also contributes to the inefficient use of inspection resources. Food establishments are sometimes inspected by more than one federal agency because they process foods that are regulated under different federal laws or because they participate in voluntary AMS or NMFS inspection or grading service programs. Although each federal agency has different responsibilities, their inspection tasks are basically the same. As a result, the inspections are often duplicative.

### Establishments Are Inspected by More Than One Agency

Individual food establishments inspected by FDA, FSIS, AMS, or NMFS may be inspected by more than one of these agencies because each agency has jurisdiction over different foods. Establishments that produce both FDA- and FSIS-regulated products, for example, are inspected by both agencies. Likewise, establishments that participate in one or more of the voluntary inspection and grading programs are inspected by the grading agencies as well as by the regulatory agency.

Duplicative inspection efforts have been a long-standing problem. In our January 1976 letter to the Administrator of the Animal and Plant Health Inspection Service[3] discussing federal food inspection activities in Michigan, we said that FDA's and the Inspection Service's inspections potentially overlapped to a significant extent. At that time, we recommended that the agencies determine the extent to which inspection efforts overlapped and, as appropriate, attempt to eliminate redundant inspection efforts.

We found duplication of inspections to still be a problem. Between October 1, 1987, and March 31, 1991, approximately 6 percent, or 514, of the 8,653 food establishments inspected by FDA in the six states in our review were also inspected by one or more of the other federal agencies. This duplication of effort represents over $1 million in staff costs. While this duplication appears relatively small at 6 percent, it is significant when viewed in light of what FDA officials maintain are limited agency resources and other critical priorities. Also, although our findings cannot be projected nationally, such potentially redundant federal inspections could

[3]The Animal and Plant Health Inspection Service was the USDA agency that administered the meat and poultry inspection acts before FSIS was established.

be occurring in the other 44 states, since the same policies and procedures for determining inspections apply.

In addition to duplicating the inspections conducted by other federal agencies, FDA inspections, to some extent, have overlapped inspections that it had contracted to the states. Since FDA considers such contract inspections equivalent to its own, FDA, in effect, duplicated its own inspections when it inspected establishments following state contract work. For example, under its fiscal year 1991-92 seafood plan, FDA set a goal of inspecting all domestic seafood processors. During fiscal year 1991, FDA's Chicago District Office inspected eight seafood processors that FDA had paid the state of Illinois to inspect under its fiscal year 1991 state inspection contract. In three cases, FDA inspected the seafood establishments less than 1 month after the state had inspected the same establishments. One of these establishments was also participating in NMFS' grading program and thus was subject to at least weekly NMFS sanitation inspections.

While FDA's inspections focused on completing questionnaires for its seafood survey, FDA also performed limited inspections for compliance with sanitation requirements and good manufacturing practices during these visits. Thus, to some extent, FDA duplicated the work it had paid the state to do and that NMFS was also doing rather than contracting with the state to complete the seafood survey or directing the state to refrain from inspecting the seafood processors that it planned to inspect.

FDA officials responsible for food establishment inspections agreed that FDA and other federal agencies inspect many of the same firms and that the inspections cover many of the same areas. However, FDA officials pointed out that (1) FDA has been assigned regulatory responsibility for these establishments, (2) grading agency programs are voluntary and firms enter and leave the programs as they please, and (3) FDA's inspections cover areas not covered by the other agencies.

However, not only does FDA frequently contract with state agencies to complete its inspections but it has also entered into an agreement under which it will rely on another federal agency, AMS, to inspect certain plants producing egg products. In June 1990, FDA entered into an inspection arrangement with AMS for regulated egg-product plants that also process FDA-regulated foods. FDA and AMS agreed to initially perform a joint inspection of the plants so that FDA could make AMS aware of situations that could violate the FFDCA. Thereafter, under the agreement, AMS would

inspect the plants and notify FDA of plant conditions in violation of requirements. Although FDA has retained the right to inspect firms when it believes such inspections are warranted—such as investigating consumer complaints or referrals from other federal agencies—AMS serves, in effect, as the lead federal food agency responsible for inspecting these plants.

Furthermore, although the programs of grading agencies are generally voluntary, in some instances firms are required to have their products graded. For example, according to AMS officials, federal marketing orders for raisins, dates, and olives, developed in conjunction with industry, require that California processors have their products graded by AMS. Grading agencies could also notify FDA when establishments withdraw from the programs, giving FDA an opportunity to again make those firms subject to FDA inspection while avoiding unnecessary and costly duplication.

Finally, although FDA inspections include some special tasks, most tasks are duplicated by other agencies and any special inspection tasks specific to FDA could be incorporated into agencies' inspection procedures.

## Agencies Perform the Same Basic Inspection Tasks

Although FDA inspections contain some special tasks, many of the inspection tasks are duplicated by other agencies. Our analysis of 18 food establishments receiving duplicative federal inspections showed that the same basic inspection tasks performed by FDA are also performed by another federal agency on a much more frequent basis. The federal agencies' inspections primarily emphasized sanitary procedures, conditions, and controls. For example, in 12 food establishments that were inspected by both FDA and FSIS, FSIS performed the equivalent of 35 out of the 43 inspection tasks performed by FDA. Similarly, in 6 food establishments inspected by FDA and NMFS, NMFS performed the equivalent of 33 out of 42 inspection tasks performed by FDA. For these equivalent tasks, FDA inspections clearly duplicate NMFS and FSIS inspection tasks, which are performed daily, weekly, or monthly, depending on the particular task performed and the plant inspected.

Items specifically covered by FDA inspections but not mentioned in the FSIS and NMFS inspection records we analyzed included reviews of (1) plumbing, sewage disposal, air quality, and ventilation systems; (2) insect and rodent control programs; (3) storage, handling, and disposal procedures for utensils, equipment, and single-service items; (4) chemical, microbiological, or extraneous material-testing procedures; (5) food and

color additives; (6) storage and disposal practices for foods that have exceeded their expected shelflife; (7) weighing and measuring equipment and practices; and (8) labels used on product packages.

Although one or more of these items were not specifically mentioned in the FSIS and NMFS inspection records that we reviewed, the agencies still inspected them. For example, FSIS reviews the facilities and equipment of a plant before the plant begins operations and periodically from then on. FSIS also preapproves labels to be used on its regulated products. Therefore, FSIS scrutinizes the plants' plumbing, sewage disposal, air quality, ventilation systems, and product labels. NMFS officials also pointed out that in accordance with the agency's manual of Federal Sanitation Standards for Fish Plants, NMFS inspectors perform all of these eight inspection tasks periodically throughout the year. For example, NMFS inspectors also routinely examine product labels to ensure that they properly identify the product and that the package contains the correct quantity.

Officials at the FSIS, AMS, and NMFS field offices we visited agreed that FDA inspections overlap their inspections. According to these officials, any inspection tasks specific to FDA could easily be incorporated into their agencies' inspection procedures.

Overlapping inspection responsibilities can lead to wasteful and inefficient practices. The lead FSIS inspector at a frozen-food firm where five full-time FSIS inspectors were assigned told us that FSIS inspected every aspect of the firm's facilities and operations, except for a 20-foot square glass enclosed room. That small room was where traditional meat sandwiches—the firm's sole product under FDA's jurisdiction—were processed. The FSIS inspector said she and other FSIS inspectors could easily inspect this small operation at virtually no additional cost. She pointed out that these products would then receive much greater regulatory attention than they do under FDA's direct jurisdiction, under which inspections take place on average once every 3 to 5 years.

Moreover, federal marketing orders, as previously mentioned, require that California processors of raisins, dates, and olives have their products graded by AMS. As a result, AMS has about 20 inspectors assigned full-time to one large raisin-packing plant, who, as part of their duties, inspect the plant's sanitation daily. Yet, FDA still inspects this plant. An AMS official responsible for the inspection and grading of processed products said that AMS could easily include FDA's inspection requirements in its inspections. For example, he said that AMS routinely examines products purchased by

the federal government to ensure that they meet all contract specifications, including the proper use and labeling of food and color additives.

## Conclusions

Federal food safety and quality inspection resources are not efficiently used, in part because FSIS continues to inspect meat-and poultry-processing firms daily rather than using its current legislative authority to adopt risk-based or discretionary inspections. Rather than reducing product safety, discretionary inspection could lead to overall safer products and help to reduce costs because scarce federal inspection resources would be redirected from low-risk operations to areas that may need greater coverage because they present a higher risk potential. FSIS' discretionary inspection authority, however, will expire in November 1992 unless the authority is extended through legislation.

Duplicative inspections by federal agencies also result in an inefficient use of resources. While federal agencies have overlapping safety or quality responsibilities for some food commodities, the vast majority of inspections cover the same areas—primarily sanitation. Instead, a single agency could take the lead responsibility for inspecting to ensure that food establishments comply with all federal food safety laws and regulations, ceding when necessary to the enforcement authority of the appropriate agency if violations are found. FDA has already entered into an arrangement with AMS for certain egg-product plants under which AMS is responsible for performing inspection tasks but FDA retains the right to inspect the firms when warranted. Such agreements have the potential to reduce duplicative inspections and thus save inspection resources without compromising food safety standards.

## Recommendations

We recommend that the Secretaries of Agriculture, Commerce, and Health and Human Services enter into agreements that require the agency most frequently visiting a food-processing plant to act as the lead federal inspection agency. The lead agency would perform the inspection tasks, if any, required by the other agencies and request plants to make changes to comply with all federal food safety laws and regulations. However, when necessary, the lead agency would refer continuing violations to the responsible regulatory agency to pursue corrective action in the courts. In addition, the agency with regulatory responsibility would retain primary responsibility and inspect plants when warranted, such as to respond to consumer complaints or to follow up on referrals made by other agencies.

## Matter for Congressional Consideration

To make more efficient use of federal food safety resources, the Congress may wish to consider extending FSIS' discretionary inspection authority and requiring FSIS to implement a discretionary inspection program for meat and poultry processors.

# Federal Agencies Do Not Effectively Coordinate Their Food Safety Activities

Federal food inspection agencies have entered into more than 25 coordination agreements that generally direct the agencies to notify each other of unsanitary conditions, poor manufacturing practices, or adulterated foods found during inspections. The agreements are intended to overcome inefficiencies resulting from the agencies' dispersed responsibilities by ensuring that food safety problems are corrected when problems are identified by one agency but which require another agency to resolve. In spite of these agreements, agencies do not always notify each other when they identify problems or, once a referral is made, do not always promptly investigate identified problems. As a result, unsanitary plants continue to operate, and firms market contaminated foods. For example, 131 seafood plants, refused grading services by NMFS because they failed to meet NMFS' sanitation standards, may still be operating unsafely because NMFS did not refer these plants to FDA. Even when agencies made such notifications—known as referrals—FDA did not investigate about one-third of them.

Referrals were not always made because the agreements are sometimes out-dated, do not specifically require referrals, lack specifics on how referrals should be made, or have no staff assigned to oversee implementation of the agreements. Referrals were not always promptly investigated because FDA, the regulatory agency responsible for investigating most referrals, lacks investigation resources and an adequate system for assigning and tracking referrals.

## Dispersed Food Safety System Depends on Coordination and Cooperation

The federal agencies with different food safety responsibilities and authorities depend on coordination and cooperation to avoid duplication and/or gaps in coverage, deal effectively with emerging cross-cutting issues that are under the jurisdiction of more than one agency, and take appropriate regulatory enforcement action against unsanitary establishments and contaminated foods. The five agencies with major food safety or quality roles have entered into more than 25 written agreements that generally set forth policy and guidance for handling food safety problems identified by one agency but that another agency must resolve. Agencies with voluntary inspection and grading service programs, such as NMFS, AMS,[1] and FGIS, generally have no authority to enforce good manufacturing practices and food safety standards. At most, these agencies can withdraw their grading services in an attempt to get establishments that violate standards to comply with food safety regulations. Since such actions may have little or no impact, the grading

[1]AMS is primarily a grading agency, but it has regulatory responsibility for eggs and egg products.

agencies must refer identified problems to the responsible regulatory agency for follow-up action. For example, one coordination agreement between NMFS and FDA directs NMFS to notify FDA when NMFS finds serious sanitation problems while inspecting seafood plants. Since NMFS' seafood inspection program is voluntary, NMFS has no authority to require an unsanitary seafood plant to clean up its operation.

FDA, FSIS, and in some instances AMS, have agreed to reciprocate by notifying each other or the appropriate grading agencies when inspections or complaints identify food safety problems. Officials of the grading agencies said that they need to know about problems that FDA finds in plants participating in their programs so they can verify that the problems are corrected. Such notification is important because FDA generally does not reinspect the firms until its next routine inspections, which may not take place for another 3 to 5 years.

## Unsanitary Conditions May Not Be Corrected Because Referrals Are Not Always Made

Although officials of all the agencies generally recognize the need for prompt referrals of food safety problems to the responsible agency for action, such referrals are frequently not made. As a result, unsanitary conditions may go uncorrected. Agencies say they do not always refer problems to other agencies because the agreements are outdated, do not require referrals, lack specific procedures for making such notifications to other agencies, or have no staff designated to oversee implementation of the agreements. Also, some grading agency officials were unaware that referrals were required and were reluctant to report food safety problems to FDA for regulatory action because they perceived that such referrals could cause establishments to drop out of their voluntary programs.

### Agencies Are Not Making Referrals Required by Coordination Agreements

In fiscal years 1988 through 1991, NMFS conducted a total of 394 initial sanitation inspections on seafood processors that applied for NMFS' voluntary seafood grading and inspection services. About half, or 198, of the 394 plants failed the inspection and were denied NMFS' grading services. However, NMFS officials did not bring these unsanitary seafood plants to the attention of FDA, the agency with regulatory responsibility for corrective action. NMFS reinspected 78 of the 198 plants that failed its initial inspection and passed 67 of them. But NMFS again did not notify FDA of the 11 plants that failed its reinspection. As a result, 131 plants that failed to meet NMFS' sanitation standards may still be operating under unsanitary conditions. (The 131 plants include the 198 plants failing the initial inspection less the 67 plants passing the reinspection.)

AMS' Dairy Division and Poultry Division did not promptly notify FDA when their inspectors found unsanitary conditions at dairy and egg-processing plants. By agreement, the Dairy Division is required to notify FDA of plants where services have been suspended or withdrawn for food safety reasons. However, a March 1991 USDA Inspector General's report on dairy-grading activities found that 8 of 25 dairy plants included in its study had severe sanitation problems.[2] Although the plants eventually were suspended from the division's voluntary program, the division did not notify FDA of these problem plants. The Inspector General disclosed similar deficiencies in coordination in a report on the Egg Products Inspection Act.[3]

The coordination agreements also require FDA to reciprocate by informing the grading agencies of establishments or products in violation of standards that it identifies during its inspections. FDA, however, is not fulfilling this requirement.

To determine whether FDA made the required referrals, we examined a judgmental sample of 12 FDA inspection results. We found that FDA notified the relevant agency in only 2 of the 12 cases we examined. An official responsible for FDA inspection activities said that FDA inspectors will be reminded that such referrals are required.

## Management Weaknesses Contribute to Lack of Referrals

Agency officials cited various reasons for not referring plants with unsanitary conditions to the appropriate agency. NMFS and AMS officials cited two reasons why they did not notify FDA of plants with unsanitary conditions. First, officials from both agencies were unaware that a referral was required. For example, an AMS official responsible for all dairy inspection and grading activities said that the referrals were not made because the division's regulations did not discuss them. The official said that since he became aware of the requirement, AMS has made the necessary referrals. For example, for the 3-1/2-month period from August 7, 1991, to November 21, 1991, AMS' Dairy Division referred 15 suspended dairy plants to FDA.

Second, AMS and NMFS field staff said that they did not make the referrals because they wanted to give the failing plants an opportunity to correct

[2]Agricultural Marketing Service: Dairy Grading and Inspection Activities (Audit Report No. 01061-0012-Ch, Mar. 29, 1991).

[3]Agricultural Marketing Service: Federal Inspection Under the Egg Products Inspection Act (Audit Report No. 01061-11-At, Aug. 9, 1989.)

the unsanitary conditions. They explained that industry might stop using their services if they referred every problem plant to FDA. However, an AMS Deputy Administrator and the head of NMFS' seafood program, while acknowledging that some field personnel may share this view, told us that it is their agency's policy that referrals of uncorrected unsanitary conditions should be made to the responsible regulatory agency.

FDA officials also cited two reasons why they had not always notified grading agencies of problems. First, the coordination agreements do not specify whether a referral must be written or verbal, nor do they identify a specific contact—such as a complaint coordinator—to whom referrals should be directed. Second, no official or organizational unit is accountable for monitoring implementation of the agreements and keeping them current. Some of the agreements are over 10 years old, and generally, the only contact point or individual identified is the person who originally signed the agreement.

The agreements are generally written in broad terms and lack specifics on procedures for communicating referrals between agencies. The general nature and vagueness of the coordination agreements often make effective implementation difficult. The FDA/NMFS agreement, for example, requires NMFS to refer identified problems to FDA but is unclear about whether FDA has reciprocal referral responsibilities. The agreement requires FDA to contact NMFS about adulterated products it has seized but does not require FDA to refer products or plants that violate standards to NMFS. Furthermore, the agencies have not incorporated referral procedures into their inspectors' handbooks or other guidance.

OMB, the federal office responsible for ensuring interagency coordination, has not actively pursued improvements in the coordination of federal food safety inspections, other than encouraging the use of coordination agreements. OMB officials said that they were unaware of coordination problems in agencies' food inspections but would consider suggestions for improvement.

Overall, our review of coordination agreements showed that referrals are more likely to be made if coordination agreements are given attention by agency management and are made a part of an agency's administrative system. Such an effort involves assigning responsibility for overseeing implementation of the agreement to an individual, supplementing the agreement with separate detailed guidance issued to the agency's inspection personnel, and periodically updating the agreement and related

procedures. For example, FGIS recognized the need for specific referral procedures when in April 1986—6 months after entering into a coordination agreement with FDA—it issued separate guidance to its inspectors on how to make referrals and whom to contact. Subsequent to this change, we found that FGIS was referring identified food safety problems to FDA, as required by the FGIS/FDA coordination agreement.

## FDA Follow-up on Referrals May Not Occur or May Be Delayed

Even when referrals are made, they may not always lead to timely FDA investigations. It is FDA's policy to have its inspection staff perform follow-up investigations on referrals received from other agencies. However, FDA's inspection program priorities determine when these follow-up investigations will be performed. According to FDA officials, the agency lacks the resources to always conduct prompt follow-up investigations and does not have an adequate referral assignment and tracking system to ensure that investigations are made in a timely manner. As a result, some referrals are not promptly pursued and others are not pursued at all. Thus, potentially serious food safety problems can go uncorrected.

To determine if referrals were being investigated, we tracked a sample of 34 referrals made to FDA by grading agencies between January 1990 and November 1991 that required FDA action. Of these 34 cases, FDA did not investigate 13 and was unable to investigate 2 others until 6 weeks or more after receiving the referral. These cases included food safety problems with potentially serious consequences for consumers. For example:

- FGIS notified FDA's San Francisco district of a grain product shipment contaminated with animal filth and other foreign material. This case was never assigned to an investigator for follow-up because the FDA employee who received the referral filed it without notifying the responsible unit.
- AMS notified FDA's Dallas district of a juice-processing establishment that was denied grading services because of unsanitary conditions. The unsanitary conditions included (1) storage of stagnant and polluted water—an insect breeding ground—in an open holding tank adjacent to the processing area; (2) mounds of rubbish and other materials around the plant that provided a haven for rodents and other pests; (3) a dead, decomposing bird in close proximity to raw food stocks; and (4) rusting valves on the food- processing equipment. This verbal referral was not pursued because the employee who received the referral did not alert the unit responsible for investigating it. Five weeks after our initial inquiry, the Dallas district still had not initiated an investigation of this establishment.

- AMS notified FDA's Dallas district on March 30, 1991, that 96 cases (about 4,000 pounds) of peanut butter contained excessive levels of aflatoxin. However, the Dallas district waited until May 28, 1991—2 months after it was first notified—before investigating this matter. By the time FDA acted on the referral, the manufacturer had voluntarily diverted the peanut butter to a nonfood use. An FDA official said that the response time in this case was about average, citing FDA's other higher-priority responsibilities, such as inspecting low-acid canned food plants and seafood plants.
- AMS provided FDA's Newark district with documentation on 899 cases of contaminated tomato paste on March 18, 1991. However, the Newark district did not investigate the referral until May 1, 1991—6 weeks after being notified. FDA could not explain why the investigation was delayed. When FDA investigated the referral, it found that the adulterated product had been exported to Canada. Therefore, FDA dropped the investigation because the product was no longer under FDA's jurisdiction.

FDA's failure to investigate referrals was also cited in a January 1992 study by a FDA task force on the use of animal drugs in food-producing animals. The task force reported that despite the "very high priority" FDA assigned to illegal residues in food-producing animals, FDA—the agency with regulatory responsibility—investigated 2,407, or less than 20 percent, of the 12,787 cases reported by USDA in 1989 and 1990.

## Conclusions

Despite more than 25 coordination agreements intended to overcome problems inherent in the dispersed federal food inspection system, unsanitary plants have continued to operate. If coordination agreements are to be effective, it is important that they be updated periodically and drawn up with specific instructions not only on the responsibilities of each agency with regard to referral requirements but also on the method for making such referrals. Otherwise, the present situation—in which agencies sometimes fail to make referrals because agreements are outdated or do not include information on how to contact the responsible agency—could continue. Ensuring that referral procedures are incorporated into inspectors' handbooks could help eliminate the instances we found in which inspectors were not aware of the requirements. When FGIS issued guidance to its inspectors, for example, the agency consistently complied with the requirements of its agreement with FDA.

Furthermore, referrals serve their purpose only if the responsible agency follows up on them in a timely manner. If FDA is to ensure that actions on

referrals from other agencies are not delayed, it is important that the agency have an adequate assignment and tracking system. Such a system could be used to keep both FDA and the referring agency informed of the status of the referral, and allow FDA to establish priorities for using its limited resources to address food safety problems with potentially serious consequences for consumers.

## Recommendations

To help ensure effective coordination between federal agencies with food safety and quality responsibilities, we recommend that the Secretaries of Agriculture, Commerce, and Health and Human Services evaluate and revise as necessary all current coordination agreements related to food safety and quality. Specifically, the Secretaries should direct the agency heads to revise the agreements, as necessary, to (1) define the responsibilities of each agency, (2) require the referral of firms with unsanitary food-processing conditions or unsafe food products to all agencies with regulatory oversight or grading responsibilities, (3) specify how and when referrals should be made, and (4) identify the individual or office to which referrals should be made. In addition, the Secretaries should direct the agency heads to periodically, but no less than annually, review their respective coordination agreements and update them when necessary.

We also recommend that the FDA Commissioner and the Secretaries of the Departments of Agriculture and Commerce incorporate referral procedures into inspector manuals or handbooks to assist agency personnel in making referrals properly and in a timely manner.

Finally, we recommend that the FDA Commissioner (1) develop a formal system to track referrals received from other agencies, (2) establish minimum times for follow-up action on referrals, and (3) periodically advise the referring agencies of the status of active referrals.

# Revamping the Federal Food Safety Inspection System

Differing regulatory approaches, jurisdictional conflicts among agencies, and the inability to reallocate resources across agencies have hampered and continue to impede inspection efforts to address public health concerns associated with existing and newly identified food safety risks, changing consumer diets, and emerging food technologies. Although implementing the recommendations in the previous chapters will help improve the federal food safety inspection system, improvement efforts have historically fallen short because the agencies have continued to operate under different food safety statutes and appropriations. Moreover, it is unlikely that major, long-term improvements will occur unless basic changes are made to the overall federal food safety and quality inspection system. A uniform, risk-based inspection system could help ensure a safe food supply, reduce or eliminate duplication, enhance coordination, and improve consumer confidence in the safety of the nation's food supply. Alternatives for achieving this uniform, risk-based inspection system include creating a single food safety agency to administer a uniform set of food safety laws, creating a uniform set of food safety laws to be administered by the current federal food safety agencies, and developing a model for risk-based inspection and food safety enforcement.

## Previous Efforts to Correct Deficiencies Have Fallen Short

During the past two decades many organizations, including GAO, have issued reports detailing the need to improve the federal inspection and regulatory system for ensuring a safe, high-quality food supply. Yet despite recognition of this need by federal food safety agencies, consumer groups, and industry, major improvements have not been made largely because the agencies continue to operate under the different regulatory approaches contained in their basic laws.

In 1977, the Senate Committee on Governmental Affairs said the following in its report on the complicated nature of food safety regulation:

"Increasingly the human diet has come to consist of highly processed foods, some containing meat and some with no meat ingredients. Existence of divided responsibility for regulating production of these foods has resulted in a regulatory program which is often duplicative, sometimes contradictory, undeniably costly and unduly complex."[1]

The report further noted that when agencies shared responsibilities, authority to accomplish the task was often unclear and incomplete in some areas, resulting in serious problems "falling through the cracks."

[1]Study on Federal Regulation, Regulatory Organization, United States Senate, Committee on Governmental Affairs (Dec. 1977, Vol. V, p. 114).

Other reports in the early to mid-1980s pointed out the wide differences in USDA's and FDA's regulatory enforcement powers, citing FDA's general lack of authority to require the registration of firms involved in interstate commerce or to detain adulterated products.

The need to base the frequency with which inspections take place on the risk posed by the particular product, process, and processor, instead of on legislative mandates, has also been repeatedly noted. In 1977, we recommended that the Secretary of Agriculture develop criteria for setting optimal inspection frequencies for meat- and poultry-processing plants. The USDA Inspector General recommended in 1986 that FSIS consider adopting a risk-based inspection system for such plants. However, implementing these changes without making other, more fundamental changes would represent only a piecemeal improvement that ignores the need for a comprehensive, coordinated food safety inspection system. For example, savings resulting from the implementation of a risk-based inspection program could not easily be redirected to FDA inspections of foods posing similar risks because FSIS and FDA funding come from different appropriations and therefore cannot be transferred between agencies. Thus, the implementation of a risk-based FSIS inspection system would do little to address the large difference in agency resources, under which, as noted in chapter 1, in fiscal year 1991 FSIS devoted about 9,000 staff years to oversee about 6,100 establishments, while FDA devoted about 255 staff years to oversee an estimated 53,000 food establishments.

The need for efficient federal inspection programs that ensure food safety has been increasingly recognized in recent decades, yet the agencies have had only limited success in developing approaches for effectively eliminating duplicative efforts. In January 1976, we recommended the elimination of redundant FDA and FSIS inspection efforts. Over 13 years later, an August 1989 USDA Inspector General's report called attention to the continuing duplication of efforts when it urged FDA to rely on AMS inspections of AMS-regulated egg product plants. As we pointed out in chapter 3, although FDA has made some progress, inspections are still significantly duplicative, in light of FDA's limited inspection resources.

Furthermore, as noted in chapter 4, despite the more than 25 interagency coordination agreements, unsanitary plants have continued to operate, and contaminated food has been marketed because referrals are not always made or promptly investigated. We raised a similar issue when we reported in 1981 that, in regulating pesticide contaminants in food, FDA did

not maintain records of referrals or follow up to determine the status of investigations.[2]

The issue of coordination and cooperation goes beyond the simple process of communicating information on food safety problems from one agency to another. Coordination and cooperation are also vital if scarce resources are to be used efficiently and if coherent federal policies are to be developed for responding to emerging cross-cutting food safety issues like salmonella control. In 1978, the President's Reorganization Project reported that FDA, the Environmental Protection Agency, and USDA each had partial responsibility for keeping toxic contaminants out of the food supply.[3] The report concluded that coordination was difficult and no agency had sufficient resources to do the job. In 1983, we reported that agencies had not always updated older interagency agreements to reflect organizational changes that resulted in shifts in responsibility between various agencies. In our recent report on federal efforts to control salmonella in eggs,[4] we described actions of federal agencies that were more concerned with protecting their own jurisdictions than developing an effective federal program to deal with this major public health issue.

Jurisdictional disputes are not restricted to the federal agencies tasked with overseeing the safety of the nation's food supply. Congressional conflicts about jurisdictional issues occurred in 1990 when two Senate and three House committees could not agree on which agency should be given inspection duties in a seafood inspection bill. The bill died before the Senate and House convened a conference committee to produce a compromise bill.

Consumer groups and industry officials recognize that different regulatory approaches and inconsistencies in the frequency of inspection and enforcement authorities have systematically hindered efforts to improve the current federal food safety system.

- Representatives of the Grocery Manufacturers of America, whose members account for 80 percent of the packaged food industry, said that if starting from scratch, no one would develop the system we have today.

[2]Stronger Enforcement Needed Against Misuse of Pesticides (GAO/CED-82-5, Oct. 15, 1981).

[3]Food and Nutrition Study Final Report, President's Reorganization Project, Office of Management and Budget (Dec. 19, 1978).

[4]Food Safety and Quality: Salmonella Control Efforts Show Need for More Coordination (GAO/RCED-92-69, Apr. 21, 1992).

They believed, however, that given the existing political climate, major changes are highly unlikely.

- Representatives of the National Food Processors Association, which has about 500 member companies that account, in dollar terms, for between 60 and 80 percent of total U.S. processed foods, said that there is no scientific justification for the difference in treatment of processed foods regulated by FDA and USDA.
- Representatives of the American Meat Institute, the largest U.S. trade association for meat products, whose members account for 90 percent of all meat products consumed in the United States, said that they would like to see a total revamping of the federal regulatory system. They argued that the dispersal of regulatory authority among federal agencies causes problems for the meat industry, and that it is not unusual for as many as three or four federal agencies to be involved in a single issue.
- A former Assistant Secretary of Agriculture who provides consulting services to consumer groups and the food inspectors' union said that the federal regulatory structure as it applies to food safety is illogical and the United States can no longer afford to run two parallel programs doing similar things.

## Options for Modifying the Basic Federal Food Safety Inspection System

The basic laws governing the different regulatory approaches used by the federal agencies, the fragmentation of responsibilities, and separate appropriations have resulted in inconsistent inspections, different enforcement authorities, and duplicative and overlapping efforts. Furthermore, the extensive coordination needed to resolve these inconsistencies has historically been lacking. Therefore, a basic revamping of our food safety inspection system may be needed. Among the options for achieving this basic change are (1) creating a single food safety agency responsible for administering a uniform set of food safety laws, (2) creating a uniform set of food safety laws to be administered by the current federal food safety agencies, or (3) establishing a "blue-ribbon" panel to develop a risk-based model for inspection frequency and food safety enforcement. Each of these options has advantages and disadvantages.

### A Single Agency Could Administer a Uniform Set of Laws

In 1977, the Senate Committee on Governmental Affairs recommended that the responsibility for food regulation be unified under a single federal agency and federal statute. The Committee explained that appropriate overall organization of the regulatory structure can help government to operate at maximum efficiency and economy, thus avoiding conflicts and

duplication of effort. This argument has become even more convincing since 1977 as money for new programs has dwindled, and new initiatives have been funded only from savings obtained by reducing inefficiency, waste, and outmoded or unnecessary efforts. We recognize that the agencies have responsibilities—such as setting food safety and quality standards and approving new food additives—that go beyond food safety and quality inspections that must be considered before inspection activities could be consolidated under one agency. However, while we did not include these other activities in our review, approximately two-thirds of the agencies' budgets are devoted to food safety and quality inspection and testing activities.

Two key elements are necessary to a set of uniform food safety laws. First, the laws should include provisions for inspections based on the health risk inherent in the commodity, the processing operation—canning, drying, freezing, etc.—and the processor's record of compliance with federal food safety regulations. Second, the laws should include the powers deemed necessary for effective oversight—such as registration authority—and effective enforcement—such as detention authorities and civil penalties.

Making a single food safety agency responsible for administering a uniform set of federal laws would (1) increase efficiency by eliminating overlapping and duplicative efforts; (2) eliminate illogical and inconsistent treatment of food products that pose similar risks; (3) avoid problems historically associated with interagency agreements; (4) consolidate federal food safety appropriations, thus allowing the agency to target food safety resources where they are most needed; and (5) reduce administrative costs by eliminating redundant overhead and by realizing economies of scale.

On the other hand, making a single agency responsible for administering a uniform set of federal laws would require major legislative and organizational changes that may be difficult to achieve. Furthermore, merging the various federal food agencies, which have profoundly different organizational cultures, into a single cohesive organization may be too disruptive.

## Multiple Agencies Could Administer a Uniform Set of Laws

A second option would be to preserve the current agency structure but to enact a uniform and comprehensive set of food safety laws. The President's Reorganization Project's 1978 Food and Nutrition Study concluded that

"... unification, accompanied by legislation to standardize regulatory approaches, powers, and penalties, could not only provide an environment for correcting longstanding problems, but also significantly reduce Federal expenditures."

Multiple agencies administering a uniform comprehensive set of food laws would achieve some of the benefits of the first option—namely, it would eliminate the current illogical and inconsistent treatment of food processors and food products posing similar health risks. However, this option would not address (1) the problem of overlapping and duplicative efforts, (2) the complications inherent in interagency agreements, (3) the current difficulty of targeting food safety inspection resources to areas where the need is greatest by reallocating them among the agencies, or (4) the need to reduce administrative redundancies and realize the resulting economies of scale.

Revising the current food safety laws is also a formidable task, even without addressing the agencies' overlapping jurisdictions. If multiple agencies were retained, they would likely follow the current commodity-based regulatory structure, in which each agency is responsible for specific foods. Therefore, the potential for overlapping and duplicative efforts would remain because plants frequently process several different food products that are regulated by different agencies.

Multiple agencies would still operate under separate appropriations, precluding reallocation of resources from one agency to another. Consequently, resource savings achieved by one agency, such as those available from a discretionary inspection program based on health risk for meat and poultry processors, could not easily be redirected to foods regulated by another agency.

To overcome this waste of resources, agencies would continue to use interagency coordination agreements. However, emerging food safety concerns, public consumption patterns, and technological changes can outpace changes to the agreements and thus reduce their effectiveness. Agencies' defense of their own parochial interests, which are inherent to a system of dispersed responsibilities—as we reported in a previously cited review of salmonella contamination of eggs—also reduce the effectiveness of efforts to coordinate activities.

Finally, under a multiple-agency system, each agency would be required to maintain its own facilities, administration, personnel, and other support systems. As a result, duplications would occur, and cost reduction

opportunities would be missed. For example, each food safety agency currently maintains its own testing laboratories and scientific research capability.

## Developing a Regulatory Model

A third option would be to establish a blue-ribbon panel to develop a regulatory model for federal food safety oversight. The model would provide the guidance needed to rationally allocate resources and determine inspection frequencies and enforcement authorities based on the public health risks of the foods and processes involved. In its 1979 report on food safety policy,[5] the National Academy of Sciences concluded that the food safety laws were complicated, inflexible, and inconsistent in implementation, and that food safety policy merited thorough periodic review.

A regulatory model for federal food safety oversight would have the potential to eliminate the inconsistent treatment of food products posing similar health risks, thus promoting a more efficient allocation of inspection resources and providing the enforcement powers needed to ensure a safe food supply. For example, the panel could consider whether all slaughter operations should be subject to the same level of inspection and whether all animal-processing operations should be subject to daily inspection or whether processing operations should be subject to inspection based on the nature of the risks posed by the operation. A panel composed of knowledgeable food safety authorities from the scientific, industrial, consumer, and government communities would increase the likelihood that the resulting regulatory system would gain wide acceptance.

Similar panels have been used in the past to address individual food safety issues. For example, in 1983, FSIS asked the National Academy of Sciences to convene a panel of experts to evaluate the scientific basis of the system for inspecting meat and poultry products. In 1985, FSIS asked the Academy to convene another panel to develop a risk-assessment model applicable to the poultry production system and to outline how the model might be used to evaluate poultry inspection procedures. The results of these efforts form a key element of FSIS' current initiative to modernize its meat and poultry inspection systems.

[5]Food Safety Policy: Scientific and Societal Considerations, Committee for a Study on Saccharin and Food Safety Policy, Institute of Medicine and the National Research Council/Assembly of Life Sciences, National Academy of Sciences (Part 2, 1979).

Inviting a panel of experts to develop a model for food safety oversight would likely be the easiest option to adopt. However, if the panel's mandate is narrowly focused and avoids sensitive organizational and legislative issues, it will have disadvantages similar to those associated with the multiple agencies, uniform set of laws option discussed above. That is, food safety responsibilities would still be fragmented. As such, a food safety model would not address the potential for overlapping and duplicative inspections, the complications inherent in interagency agreements, and the need to reduce administrative redundancies and realize economies of scale.

## Conclusions

Past efforts to correct deficiencies of the federal food safety inspection system have fallen short because the responsible agencies have continued to operate under different food safety statutes and appropriation acts. Separate appropriations prevent resources from being reallocated to improve the consistency of inspections of plants posing similar public health risks, and agency self-interest and differing regulatory approaches hinder the coordination that is needed to address health concerns associated with emerging food safety issues and changing food technologies. We recognize that the federal agencies included in our review have responsibilities that go beyond food safety inspections which must be considered. But to obtain a uniform, risk-based inspection system, basic changes need to be made to the current regulatory system. Because the federal regulatory system for food has evolved over the past century and will continue to evolve as food safety concerns emerge, it may now be time to review the structure of this system in terms of the number of laws and agencies involved and the priorities that have governed their regulatory approaches. Without such changes, structural problems can be expected to make major, long-overdue improvements highly unlikely.

Our analysis of the advantages and disadvantages of the three options indicates that creating a single food safety agency is the most effective way for the federal government to resolve long-standing problems, deal with emerging food safety issues, and ensure the safety of our country's food supply. However, we also recognize the obstacles facing those who wish to make such a major structural change in the way the federal government does business. Our present food safety system has been in place for most of this century; agencies, congressional committees, and regulated industries have developed a strong allegiance to the status quo. Consequently, it may be more realistic to place the burden of examining and weighing the various alternative approaches for reorganizing federal

inspection responsibilities and suggesting legislative changes on a panel of prominent scientists, policymakers, consumers, and other experts. This approach would begin the process of developing broad-based agreement on organizational and legislative changes that are acceptable in modernizing the food safety system. By relying on such a blue ribbon panel to create a model for the modernization of the food safety inspection system, the Congress may be in a better position to justify the need to implement broad-based reforms.

## Recommendation to the Congress

To develop a uniform, risk-based inspection system, we recommend that the Congress hold oversight hearings to evaluate options for revamping the federal food safety and quality system, including (1) creating a single food safety agency responsible for administering a uniform set of food safety laws, (2) creating a uniform set of food safety laws that are administered by the current federal food safety agencies, or (3) establishing a blue-ribbon panel to develop a model for inspection and food safety enforcement based on the public health risks posed by the products and processes.

# Major Legislation, Responsibilities, and Inspection Frequencies of Primary Federal Food Safety/Quality Agencies

| Agency | Major Legislation | Food Safety/Quality Responsibility | Inspection Frequency |
|---|---|---|---|
| FDA | Federal Food, Drug, and Cosmetic Act. | Regulates safety of all food products, except meat, poultry, and some eggs. | On average, once every 3-5 years. |
| FSIS | Federal Meat Inspection Act. | Regulates safety of meat products. | Continuous for slaughtering operations. Daily for processing operations. |
| | Poultry Products Inspection Act. | Regulates safety of poultry products. | Continuous for slaughtering operations. Daily for processing operations. |
| AMS | Egg Products Inspection Act of 1970. | Regulates safety of egg products and controls the disposition of restricted (e.g., cracked) eggs. | Continuous for egg-products-processing plants. Quarterly for hatcheries and egg packers. |
| | Agricultural Marketing Act of 1946. | Facilitates marketing and grades the quality of meat, poultry, dairy, fruit, nut, and vegetable products. | Varies, depending on terms of contracts. |
| FGIS | U.S. Grain Standards Act and Agricultural Marketing Act of 1946. | Facilitates marketing and quality of grain, oilseeds, pulses, rice, and related commodities. | All grain exports and, upon request, domestic grain and other products. |
| NMFS | Agricultural Marketing Act of 1946 and Fish and Wildlife Act of 1956. | Facilitates marketing and quality of fish and shellfish. | Varies, depending on terms of contract. |

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